DELIVERY OF MENTAL HEALTH CARE SERVICES AND H.R. 3037

HEARING

BEFORE THE

SUBCOMMITTEE ON
HOSPITALS AND HEALTH CARE

OF THE

COMMITTEE ON VETERANS' AFFAIRS
HOUSE OF REPRESENTATIVES

ONE HUNDRED FIRST CONGRESS

SECOND SESSION

JUNE 28, 1990

Printed for the use of the Committee on Veterans' Affairs

Serial No. 101–53

U.S. GOVERNMENT PRINTING OFFICE
33-896 ⇆ WASHINGTON : 1990

For sale by the Superintendent of Documents, Congressional Sales Office
U.S. Government Printing Office, Washington, DC 20402

H761-3

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DELIVERY OF MENTAL HEALTH CARE SERVICES AND H.R. 3037

THURSDAY, JUNE 28, 1990

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:30 a.m., in room 334, Cannon House Office Building, Hon. J. Roy Rowland (acting chairman of the subcommittee) presiding.

Present: Representatives Rowland of Georgia, Kennedy, Jontz, Stump, McEwen, Smith of New Jersey, Bilirakis and Rowland of Connecticut.

Also Present: Representative Evans.

OPENING STATEMENT OF HON. J. ROY ROWLAND, ACTING CHAIRMAN

Mr. ROWLAND OF GEORGIA. Good morning. The subcommittee will please come to order.

We are meeting today to receive testimony regarding the capacity of the Department of Veterans Affairs to deliver mental health care services. In particular, the subcommittee is interested in the DVA's ability to care for veterans suffering from post-traumatic stress disorder, as well as receiving testimony on H.R. 3037, my good friend and colleague, Jim Jontz' bill which would provide for the expansion of the services the Department provides to veterans suffering from post-traumatic stress disorder.

In addition, we will hear testimony regarding the impact on the delivery of DVA mental health services from the prescription of clozapine for mental disorders.

Senator David Pryor of Arkansas had wanted to present testimony to the subcommittee but, unfortunately, a previous commitment made this impossible. He has submitted testimony for inclusion in the hearing record. Also submitting testimony for inclusion in the hearing record is the American Association for Marriage and Family Therapy, and also, the Honorable Bob McEwen has submitted testimony. Without objection, it is ordered that be included as part of the record.

[The statements of Hon. David Pryor, the American Association for Marriage and Family Therapy, and Hon. Bob McEwen appear at pp. 78, 192 and 77.]

Mr. ROWLAND OF GEORGIA. Last week during our hearing on third party reimbursement, I alluded to the serious situation being

faced by the VA medical system. The shortage of resources for closure of beds and other reductions which leads to less care being delivered and, thus, less support for more resources. So the downward cycle continues. I recalled last week how that very cycle resulted in serious talk about closing the surgical unit at the VA medical center in my own home town.

Last week I further referred to the opportunity for the VA to show that it is an efficient, effective and economical way to provide health care. Today we will take up topics that relate to both of my points—the resource shortage cycle and the VA's opportunity to change American medicine.

The first topic is mental health. The VA is the largest provider of mental health services in the United States. It includes a full range of treatment from acute to long term, both inpatient and outpatient, from phramacological treatments to work therapy. Among its capacities that are unique in our country is its treatment of post-traumatic stress disorder, the second topic for today. Even though combat-related PTSD is most often cited; in fact, PTSD can be the psychological result of any number of stressors, such as major transportation accidents, earthquakes or storms.

The third topic is a drug called Clozaril, the Sandoz trademark name for the drug clozapine, which is used to treat schizophrenia. The major issue in Clozapine is the requirement that prescribing the drug be dependent on use of the Sandoz monitoring system. The VA has proposed its own system to monitor the side effect of Clozaril, which is granulocytopenia or agranulocytosis.

The cost of the drug, plus the required monitoring system, is about $9,000 per year per patient. At that cost, the VA either will not be able to make the drug available or will have to limit the delivery of other mental health care. There is little information about the cost of the drug independent of the monitoring system, but European experience suggests the drug cost is relatively low. If the VA can provide appropriate monitoring with in-house capacity, why should the additional cost be required?

I will now recognize my friend, the ranking minority member of the full Committee, the Honorable Bob Stump, for any comments that he may wish to make.

Mr. STUMP. Mr. Chairman, I thank you.

I would first like to welcome all the witnesses here this morning, and especially our colleague, Lane Evans, a member of the full Committee.

I have no statement but the ranking member, John Paul Hammerschmidt, could not be here today. He has a markup on another committee and I do have a statement that I would like put in the record for him.

Mr. ROWLAND OF GEORGIA. Without objection.

[The statement of Hon. John Paul Hammerschmidt appears at p. 71.]

Mr. ROWLAND OF GEORGIA. I now wish to recognize my good friend, Jim Jontz, who has the legislation relative to PTSD.

OPENING STATEMENT OF HON. JIM JONTZ

Mr. JONTZ. Thank you very much, Mr. Chairman. I do have an opening statement that I would ask be submitted for the record in full.

I will summarize very briefly by saying, first of all, thanks to you and the subcommittee for scheduling this hearing. H.R. 3037 enjoys the cosponsorship of about 116 Members of the House, including a number of the members of this committee and subcommittee. I am sincerely appreciative of the support for the legislation and the time that is devoted today to hearing a number of outstanding witnesses who will offer their perspective on what meaningful steps we can and should take in the Congress to address the PTSD problem.

As the members of this subcommittee know, the VA, at the direction of Congress, had a study conducted by Research Triangle Institute, which was completed about 18 months ago, which provided us with quantitative information about the extent of PTSD and the extent of treatment. I find the results of that study quite compelling. Some 480,000 veterans of the Vietnam conflict currently suffer from PTSD, with fewer than 10 percent of those veterans receiving assistance from the VA during 1988, the last year of the study.

Those statistics and my experience at home with veterans who suffer from PTSD and the treatment program at the Marion VAMC in Marion, IN compelled me to prepare the legislation which is before this committee today. It is a blueprint of a variety of approaches for both inpatient and outpatient care, a half-way house idea, research, training—a comprehensive approach to improving the efforts made by the DVA to address this problem.

I know there are a number of good things that the DVA is doing, but I feel that it is necessary for us on the Veterans' Committee and for the Congress to move this legislation—or some comparable piece of legislation—forward to provide a greater stimulus and direction to ensure that these veterans who served our country in combat, whether in Vietnam or some prior conflict, and are still suffering readjustment problems, get the attention that they properly deserve.

My thanks again to you, Mr. Chairman, and to all the members of the subcommittee. I know we have a number of outstanding witnesses to hear from today, starting with our distinguished colleague, Congressman Lane Evans. Let me thank you again for the opportunity to make an opening statement.

[The prepared statement of Hon. Jim Jontz appears at p. 88.]

Mr. ROWLAND OF GEORGIA. Thank you very much.

Mr. Smith of New Jersey.

OPENING STATEMENT OF HON. CHRIS SMITH OF NEW JERSEY

Mr. SMITH OF NEW JERSEY. Thank you, Mr. Chairman. I appreciate your arranging this hearing today to review VA mental health services and H.R. 3037, a bill to expand treatment for veterans suffering from post-traumatic stress disorder.

As the National Vietnam Veterans Readjustment Study found, Mr. Chairman, only one-fifth of veterans suffering from PTSD have

received treatment from the VA. Many veterans are either not aware of the services available to them, or have difficulty in first gaining VA eligibility for the services. Obviously, Mr. Chairman, outreach must be increased in order to educate veterans and to inform them of the benefits. Also necessary, however, is an increase in the availability of services and facilities to deliver treatment.

Despite a dramatic increase over the years in veterans' needs for mental health services, the VA and the Congress to some extent have not sufficiently devoted resources to this care. The VA has recently taken, however, some positive steps towards solving these unmet needs. The VA's plan to establish substance abuse disorder PTSD teams to help fill the gap in services and its MEDIPP program's recommendations for additional PTSD facilities are an indication that the VA is receptive to expanding services.

I would also like to take this opportunity to welcome our distinguished colleague, Mr. Evans, who will be presenting testimony to us, and I would acknowledge his leadership in this area since he's been in Congress

I yield back the balance of my time.

Mr. ROWLAND OF GEORGIA. Thank you.

Mike Bilirakis from Florida.

OPENING STATEMENT OF HON. MICHAEL BILIRAKIS

Mr. BILIRAKIS. Thank you, Mr. Chairman. I, too, thank you and Chairman Montgomery for taking the time to hold this hearing.

Mr. Chairman, in these times of fiscal restraint, the word attached to all of our efforts is cost, c-o-s-t. However, I believe it is of the utmost importance that we never forget the price paid by the many Americans who defended our freedom. The trauma of war is its cost, which far too many Americans must bear each day. For that reason, I strongly feel that the word "cost" should not be a part of our vocabulary when we consider veteran matters.

I welcome this opportunity to discuss H.R. 3037 because, as we all know, tragedy is not confined to the battlefield. What we learn about PTSD not only aids the veteran, who still battles with the memories of his service, but it also helps every many, woman and child who has been a victim of any type of tragedy. I am pleased that we have this time to examine the reasons why many who suffer from PTSD are not getting the very best care we can provide.

It is disturbing to me, as others have said, that a drug which has been readily accessible to patients in Europe since the late 1960s has been introduced here in the United States only since this past February, with what appears to me to be an exorbitant price tag.

Mr. Chairman, we do have the greatest obligation to provide the best health care possible, but that obligation comes with the responsibility of using our resources wisely enough so that everyone who seeks help may find it. I look forward to hearing the testimony today so we can examine the problems and continue to explore for solutions.

Thank you, Mr. Chairman.

Mr. ROWLAND OF GEORGIA. Thank you very much.

I am pleased to welcome our colleague, Lane Evans from Illinois, who is Chairman of the Subcommittee on Oversight and Investigations. He has done a lot of work in this area and has been very much involved in trying to deal with the problems that the Vietnam veterans have experienced.

Lane, we are very pleased that you're here this morning.

STATEMENT OF HON. LANE EVANS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. EVANS. Thank you, Mr. Chairman. I also appreciate your willingness to hold this hearing and to hear from so many other witnesses on this issue and several others.

I also want to thank the many Members who are here for their interest in this legislation. It's vitally important. It is not only the concern of this committee; it is one of the top priorities of the Vietnam Era Veterans in Congress Caucus, which I cochair with Martin Lancaster, in this Congress. So we appreciate you holding the hearing and attending as well.

I think my colleagues have outlined to you the statistics that are involved. We need to make this a top priority of the Department of Veterans Affairs, and the treatment of PTSD would become a top priority if we enact H.R. 3037 which Congressman Jontz has introduced. This would become a top priority because we would expand both inpatient and outpatient treatment under this bill and encourage the DVA to recruit qualified professionals to administer PTSD care.

I might emphasize that that's important to Members who have Vet Centers already. I have two very good ones, for example, serving my district in Peoria, IL and in Moline, IL. It's important because, with the creation of 40 new outreach centers by 1994, we will be able to reduce some of the service area, the populations that the current Vet Centers are dealing with right now, helping them to focus on some of these unmet needs that Congressman Smith has outlined. We're not reaching all the veterans yet, and 40 centers should help us in virtually every State reach more veterans.

In addition, the creation of 30 inpatient units will end the situation that exists now, where the inpatient units are left to the discretion basically of the local medical director. If that person feels it's important to have an inpatient unit, they will go ahead and create it, but really, they're "robbing Peter to pay Paul" because there would be a situation in which that individual medical director would have to take resources from one part of his center to devote it to inpatient treatment.

I know—and I think this is probably a problem for most Members—there is a long waiting list at so many of these inpatient units that are already in existence. We would certainly be reaching a group of people that have too severe problems for our Vet Centers to deal with in a more comprehensive and professional manner.

I have held a hearing of my subcommittee out in Indiana, as it turns out, in Jill Long's district, who is also a member of our committee. That hearing examined the treatment of PTSD by the DVA in Indiana. I would like to briefly read an excerpt from some testi-

mony that struck me. It was given by Mr. Gary White, a Vietnam veteran at that hearing. He said:

"My military training and Vietnam experiences caused both mental and emotional scars. These scars have not only affected me for 20 years (and Korean veterans for 37 years), but they have also affected those that I live with (my wife and my children), those who I socialize with (my neighbors and friends), and those that I work with. Everyone that I come in contact with will feel some effect of my mental and/or emotional condition."

I guess that's what we're really saying, is that, directly or indirectly, PTSD affects all of us. That's why I think it's necessary that we move on this legislation.

I appreciate your holding the hearing and would ask unanimous consent that my entire statement be included in the record.

Mr. ROWLAND OF GEORGIA. Without objection.

[The prepared statement of Hon. Lane Evans appears at p. 85.]

Mr. ROWLAND OF GEORGIA. I think you really hit the nail on the head when you said we're "robbing Peter to pay Paul". I think that's exactly what's been taking place. Hospital directors are scrambling around to try to meet their responsibilities and they've finally met the stone wall. You can't rob Peter any more because there's not anything there to rob.

It seems to me there has to be an infusion of funds into the system now. While we would like to have all of this federally funded, with our present budgetary constraints it seems unlikely that that's going to happen. So we need to be looking to other areas where we can get funds. One of the things we focused on last week was third party payers. We heard there may be as much as $400 million out there from insurance that we could get and bring into the system. I believe, if we can get additional money in, we can meet the personnel and equipment requirements that we need to staff the facilities that already exist.

As you know, we've been closing beds, and we've set up a vicious cycle. We close beds because there's no need to have these beds because they're not filled. Well, they're not filled because we don't have the personnel to take care of the people that come in. So you close beds, then less personnel, close more beds, and it seems to me we're moving downward.

There may be other ways we can get additional funds to come in. We can look at CHAMPUS, we can look at some other areas. It seems to me, to preserve the VA system, we have got to find a way to get additional funds to treat PTSD and many other diseases and illnesses that veterans have.

I really appreciate you coming this morning and making the statement that you did. I think it's so very important to the veterans in our country that we do all we can to maintain this hospital and health care system, providing the kind of care that they are really entitled to.

Mr. EVANS. I appreciate your efforts in trying to collect from third party insurance companies, which have an existing legal obligation to those veterans. That's something they have an obligation, I think, to pay back. So I hope that can inure to our benefit in the VA.

Mr. ROWLAND OF GEORGIA. I hope, as we move along, we can focus more attention on that area. Maybe something will come to fruition and we'll be glad that all of this has taken place.

Thank you very much for being here this morning.

Mr. EVANS. Thank you.

Mr. ROWLAND OF GEORGIA. I recognize the gentleman from Arizona.

Mr. STUMP. Thank you, Mr. Chairman. I would like to thank the gentleman, too, for his excellent testimony, while at the same time acknowledging the many, many hours of hard work he has put forth in this area. Thank you, Lane.

Mr. ROWLAND OF GEORGIA. We would like to call our first panel now: Mr. Denis Grady, who is Vice President of Operations, Sandoz Pharmaceuticals; Dr. Paul Leber, who is Director, Division of Neuropharmacological Drug Products, Center for Drug Evaluation Research, Food and Drug Administration; and Dr. Larry Lehmann, Associate Director of Psychiatry, Mental Health and Behavioral Sciences Service, Department of Veterans Affairs.

Mr. Grady, would you introduce the individual that is accompanying you?

STATEMENT OF DENIS GRADY, VICE PRESIDENT OF SALES AND FIELD OPERATIONS, SANDOZ PHARMACEUTICALS; ACCOMPANIED BY GILBERT HONIGFELD, PH.D., CLINICAL DIRECTOR, CLOZARIL PROJECT

Mr. GRADY. Thank you, Mr. Chairman, and members of the committee. My name is Denis Grady. I am Vice President of Sales and Field Operations for Sandoz Pharmaceuticals.

We wish to take this opportunity to thank all of you for the invitation to appear here this morning. We have appeared to explain and to discuss Clozaril and the Clozaril Patient Management System.

We have had various discussions on a number of occasions, but there have been a number of forums also where Sandoz' was absent. Thus, we have not always had the opportunity to present our point of view and the historical facts.

I would also like to take this opportunity to apologize for not having a written statement for all of you at this point in time. For some reason, we have no record of having received any formal invitation, and I, in fact, was on an overseas business trip found out about the invitation to the hearing Tuesday night. I came back obviously because of its importance, and to be here to explain our point of view. So we apologize for that, Mr. Chairman.

Logically, to explain the Clozaril Patient Management System from the Sandoz perspective, I think it's important to have a short and brief technical explanation on the drug itself. So I have asked Dr. Gil Honigfeld to accompany me here today. Dr. Honigfeld, at least in our shop, is known as the "father of Clozaril". His entire career at Sandoz over 15 years has been spent in the research and clinical trials that ultimately brought this drug to market. As such, he is eminently qualified to discuss the drug.

So, Mr. Chairman, if you have no objections, I would give the microphone at this point in time to Dr. Gil Honigfeld. If he can do

that, I will then explain the system and some of the questions that——

Mr. ROWLAND OF GEORGIA. Before you do that, if you would allow me to introduce other members of the panel, then we will come right back to you.

Dr. Lehmann, you are accompanied by?

Dr. LEHMANN. Miss Louise Rodriguez, who is the Director of the Clinical Pharmacy/Quality Management Division of VA's Central Office Pharmacy Service.

Mr. ROWLAND OF GEORGIA. Thank you. And Dr. Leber is here by himself.

Dr. Honigfeld, you may proceed as you desire. We will try to limit the prepared statements, or the statements you will make, to 5 minutes.

STATEMENT OF GILBERT HONIGFELD

Dr. HONIGFELD. Thank you, Mr. Chairman. I will try to remain within that time frame.

Members of the committee, we are here to discuss today generally two topics, schizophrenia and Clozaril, the new medicine for schizophrenia. I want to say a word or two about schizophrenia, which is accepted to be the most serious and most devastating of all mental illnesses. It now appears that Clozaril is the best medicine for helping those patients with schizophrenia who have failed on every other type of treatment effort in the past.

Schizophrenia specifically is a brain disease, probably a chemical imbalance, that seems to play horrible tricks on its victims. It distorts reality; patients tend to hear voices, see illusions, and they may be taunted and tormented by these visions or voices. The disease tends to attack young people, principally individuals in their teens and twenties, and tends to destroy their social life, their educational potential, and their work potential. Many patients end up spending long periods of time in hospital settings of one sort or another, where their future is generally destroyed by this disease.

The relative incidence of the disease, to put it into perspective, affects about 1 percent of the population, rich or poor, black or white, male or female. Thus, there is something over two million schizophrenic patients in this country. Most of these, of course, have no private funds for their extended treatment, since many have never even attained full vocational status. They tend to receive treatment through public funds largely, state funds, departments of mental health, Medicaid funding, and, of course, many through VA health care programs.

How is schizophrenia treated? Since the 1950s and 1960s, the principal teatment of schizophrenia has been drug therapy of one sort or another, medicines developed by companies such as our own that have revolutionized the treatment of schizophrenia, and also opened up the basic understanding of the brain disease that schizophrenia is. These medicines, thankfully, have been effective in many, many cases. The vast majority of schizophrenic patients are helped quite considerably by these medications. But there continues to be a subgroup of patients, the treatment-resistant group, perhaps 10 percent of the total population, perhaps 200,000 in this

country, who are unable to be helped at all. Many of these, despite our best efforts to get long-term, chronic patients out of the hospital and into the community, remain chronically hospitalized or living nonfunctional lives outside the hospital. These patients, both within the veterans' system and outside, remain the principal targets of the new medication.

What can we tell you specifically about Clozaril as the newest medication for schizophrenia? Since 1973, as Mr. Grady pointed out, I've had the responsibility for the clinical research testing program for Clozaril in this country. During the course of those many years, I have seen many patients, some within the veterans' system, some without, who have responded very nicely to Clozaril therapy where nothing else has helped before. We appreciated collaborating with the VA, since many of our clinical trials were conducted within the VA system, and we can report to you very fortunate and hopeful outcomes for many patients within the group for which you have principal responsibility.

We have conducted, as Dr. Lehmann and Miss Rodriguez know, a so-called compassionate need program in which patients who had no other hope of helpful therapy appealed to us for free Clozaril care. This has been provided. Today, around the country, there are about 80 patients in the VA system currently being benefited by Clozaril therapy, at our expense, and I can report that most of these appear to be doing very nicely.

Now, with all this happy news about Clozaril, why are we here today? Why is there a problem? The problem relates to Clozaril itself. Clozaril, as a drug entity, has a problem, a quite serious problem. That is, 1-2 percent of patients who receive Clozaril therapy will develop a blood reaction, and that reaction could possibly kill them. This problem, called agranulocytosis, is a loss of the white blood cells in the body. The development of this problem is unpredictable; it is a silent killer. That is, the patient has no symptoms that this problem is developing until perhaps it's too late. That is our experience abroad, where patients did die early in the 1970s and '80s, in fairly large numbers, before this problem was well recognized.

It led us to understand that the patients who died as a result of this tended to be the ones where this problem was allowed to develop unrecognized. When patients were identified through blood tests, it turned out that those were the patients who had the high survival rates. It became very clear to us then that what was critical for patients to receive the benefits of Clozaril therapy would be that they had to be monitored carefully, religiously, rigorously, to ensure that no one fell between the cracks, that this problem was not silently developing and possibly allowing infections to develop that might be hard or impossible to turn around.

Our experience here in the U.S. has been much more favorable than the earlier experience abroad. In the United States, no patient died because of this problem, although during the clinical testing program that I had responsibility for, 18 patients did develop the blood problem. In all cases, the problem was identified early, the medication stopped, and the problem was allowed to correct itself, as appears to be its natural course. The important thing for patient survival always is the early recognition of the problem.

Now, other folks have said, don't other drugs have this problem as well? That is certainly true. Many other drugs share this same type of side effect. The difference with Clozaril, and the reason for the extensive and elaborate patient monitoring system we've put in place to assure patient safety, is that the extent of the problem with Clozaril is much greater than with any other drug used in the treatment of schizophrenia, 10 to 20 times greater, or perhaps even more. So the incidence of this problem and the number of patients who may be struck by this silent killer is considerably greater than physicians working in this area have been accustomed to in the past.

To protect the lives of these young people, we have felt it necessary to assure that the safety of each patient is safeguarded by a mandatory early warning system. We have required that patients receiving Clozaril, in every environment, whether public or private, whether outpatient or inpatient, receive the drug in what we consider a "no blood/no drug" system. We have mandated that this be in place for patient safety. There is no other system like it.

We have been asked to make analogies between other types of drugs that also can produce this problem. Let me just point out that while other drugs may produce this problem, there is no other drug with this problem that we know of which is likely to be used year after year after year, often in an outpatient setting. Thus, to protect the safety of these patients, we have mandated that this system be put in place.

So, in the interest of time, I will cut any additional remarks short and, with that background, turn the microphone back to my colleague, Denis Grady, who can elaborate on the implications of this patient management system.

Thank you for your attention.

Mr. ROWLAND OF GEORGIA. Thank you very much for your testimony, Dr. Honigfeld. I think we now need to go—I allowed you past your 5 minutes because I was very interested in what you had to say. What we will do is go to other members of the panel and then come back during the question and answer period.

Dr. Leber.

Dr. LEBER. On behalf of the Food and Drug Administration, I want to thank you all for the opportunity to appear here. We have no formal statement to present. Instead, I am here to answer questions and clarify matters for the record as they arise.

Thank you.

Mr. ROWLAND OF GEORGIA. Thank you, Dr. Leber.

Dr. Lehmann.

Dr. LEHMANN. We very much appreciate the opportunity to make a presentation on behalf of the Department of Veterans Affairs with regard to clozapine. Similar to Dr. Leber, I am here to answer whatever questions the committee may have. Our formal Departmental comments on the issue of clozapine are contained in Dr. Winship's statement which will be presented later.

Mr. ROWLAND OF GEORGIA. Thank you very much.

Now I will came back to you, Mr. Grady.

Mr. GRADY. Thank you, Mr. Chairman.

Just by way of the record, I think Dr. Honigfeld made it crystal clear. Where were we a year ago, a year-and-a-half ago, before final

approval of the drug? We had a miracle drug that we wanted to get on the market because this drug will help people that don't have any other hope.

We also have a drug that kills people. There is no easier way to say it. It kills people at a rate 10 to 20 times greater than the typical drug used in this particular marketplace. And it is not in a patient that always can be relied upon. I think one has to understand that the difference between this drug and lots of other drugs also with dangerous side effects is the competency of the patient and the reliability and ability of the patient to move. It's not an acute drug, it is taken for a long period of time. It must be monitored on a national basis.

We wanted to bring the drug to the market, and we had three types of liability to consider. One, of course, is the human liability of patient deaths, which in our opinion, from a corporate standpoint, would be unacceptable. Two, the legal liability, with which you're all very, very familiar with, and third, the real liability to patients. That is, if an unacceptable number of deaths were to occur with Clozaril, the drug would be withdrawn from the market.

Now, I can only relate to you the calls we get from patients who are helped, for the first time in a long time, on Clozaril, who have to be discontinued because their white blood cell levels fall to unacceptable levels. Those people are willing to risk this life and death situation to continue to take Clozaril. That is a decision that we, as a corporation, are unwilling to make. And so we said, okay, the requirements for the system are it has to be national and it has to track patients.

Medical care, as you know, in America is practiced on a community basis. There are individual institutions, there are individual practices within cities, within communities, that can adequately monitor a drug. But, if the patient moves, if the patient travels, the ability to track that patient does not exist. Part of the Clozaril Patient Management System, and the reason there is a national contract, is so that we can track all patients across the country, regardless of movement, so that those patients that fall prey to the blood disorder will not be rechallenged on the drug. Because those that do, a heavy percentage of those that have had a previous problem will have that potentially fatal problem much faster than an ordinary patient, and the risk of a fatality is much, much higher.

So we surveyed. We asked lots of people their opinions. We asked companies to be involved in the system on a national basis. Most chose not to take part in the Clozaril Patient Management System. Either they had not the resources to do it, were not willing to commit the resources to do it, or had no access to a national database with which they could follow patients and assure patient safety.

That's where we were and that's why we chose the highest quality monitoring system we could get, in an effort to protect potential patients.

Where are we now, after the fact? We have been told that physicians lost their involvement with patient care. The fact is, the physician must enter a patient in the Clozaril Patient Management System. The physician is notified if a patient cannot be found or, when a home health care person visits the patient and they are not

there. The physician is directly informed. Should we see the beginnings of a serious blood disorder, the physician is made available to other medical consultants, should that be necessary, in outlying parts of the country in an effort to treat patients that are stricken with this blood disorder. So the physician maintains 100 percent control of the patient.

We have been told and have heard that pharmacists are excluded from the traditional pharmacist/patient relationship. The fact is, in the institutional setting, Caremark is a distributor to the hospital pharmacy. Hospital pharmacists then distribute the drug to hospitalized patients through their normal channels.

In the case of consultant pharmacists dealing with mental health units and/or VA patients, the consultant pharmacist is also the conduit through Caremark for distribution of the drug to patients. They must, of course, provide the blood sample so that we know on each subsequent week that an adequate blood test was taken before the drug is dispensed.

In the area of community pharmacy, the community pharmacist is not involved in the direct distribution of the drug. But at the patient's request, if they use a pharmacy for other medications, as many patients of this type do, then we will send the information to that community pharmacist to be entered into the patient's drug profile so that that pharmacist will be able to monitor the drug's potential interactions in taking other drugs.

Costs. I can appreciate the Representatives' comments. Every time we talk about health care, we talk about costs. It is always in the arena of cost containment. Much has been said about the European costs, the costs of the drug. I think to make the comparison of the $9,000 per year cost versus a $35 or $40 per week cost in Europe is, to a certain extent, comparing apples and oranges.

For example, in the U.K., which has a nationalized medical system, the drug is sold separately, but only through certain pharmacies, because the National Health Service picks up the cost of blood levels, blood testing, and home health care. So the drug is sold separately. If, in fact, we take the costs, for example, in Great Britain, and convert those costs and add them to the drug at maximum dose, the British cost for the entire Clozaril Patient Management System is $200 a year more than the cost here in the U.S.

But I think, more importantly, than just comparing those costs and the apples and oranges, because the health care systems are different around the world, is the other side of that scenario that the Representative alluded to, and somebody else did, and that's cost effectiveness. As a physician from Michigan said, which is a county-based mental health system, we are reimbursing for Clozaril and we are using Clozaril because our county commissioners found out a long time ago that $172 a week beats $300 a day in the institution.

Of the studies that have been done, the costs savings are significant on the inpatient setting, even taking into account increased levels of care as patients improve, and on an outpatient basis. Data from California would indicate that for every 137 patients that were successful on Clozaril therapy, the State of California and the Federal Government, through the Medicaid system, would enjoy a

potential savings of one million dollars a year. That's after paying for the drug.

I bring the cost effectiveness up, and I'm not going to allude to the quality of life issues, which I think, when you have heard and seen the efficacy of this drug, that clearly, those issues have to be considered also for the drug use at best, and at worst, a new hope for people who have had no hope.

I should also say that currently we are supporting 1,400 patients at total cost to Sandoz—those are patients who are in compassionate need programs and clinical programs, that have been unable to afford the drug. We will be extending that to 500 patients more, and almost 100 of the original "compassionate need" patients are VA patients. We are attempting to do the most responsible thing that we can do in preserving patient accessibility to the drug Clozaril and not intervening in treatment or causing relapse in many of these patients.

The future. We would hope, with the national database, that as we roll out and learn more and get more reliable information about the drug, that we may learn that the monitoring, as it exists now, with the cooperation and, of course, acquiescence of the Food and Drug Administration, that we would be able to make different recommendations about the monitoring and the frequency of monitoring of the blood. We don't know that. Many people have said at this point in time we should, we shouldn't, you shouldn't, and you don't have to.

The fact is, the drug has only been available for 4 months. There is not enough data yet compiled on the drug to make far-ranging statements about whether weekly blood monitoring is essential to patient safety or not. In a few months, perhaps we will have enough data to be able to submit and evaluate good solid data to know if blood monitoring frequency needs to be where it is at the moment. Reduced frequency of testing would significantly reduce costs.

We engaged in discussions with the Department of Veterans Affairs, and we did reject the system that the VA proposed to us. And let me explain why, because it was not a rejection of the quality of service administered by the VA hospitals.

Through the pilot projects and the clinical trials with Clozaril, our goal of patient safety, using the Clozaril Patient Management System, is over 99 percent, 99 percent compliance with "no blood/no drug," which translates to patient safety. We know that's been successful, by the way, because currently, this early on, and with very few patients in the system, we have saved nine people.

Mr. ROWLAND OF GEORGIA. Mr. Grady, we are past the 5 minutes at this point. There will be members who will want to ask questions, and I'm sure much of what you want to say will come out during the questioning.

Mr. GRADY. I apologize, Mr. Chairman.

Mr. ROWLAND OF GEORGIA. There is no doubt that schizophrenia is a horrible disease, and I commend Sandoz for what they have done in the development and marketing of this drug. Because while phenothiazines do a good job in some patients, psychotropic drugs, other than those two, this drug has really, from my understanding, done a lot to help those people who would not otherwise be helped.

So I appreciate what Sandoz has done. The research that is going on now is really unbelievable, particularly in the area of mental illness, as well as many other areas.

I understand what you're saying about the liability problems, the human liability and the legal liability, the fear that the drug may be removed from the market if it's not carefully monitored. I have some questions that I do want to ask about this, though.

Let me ask you, Dr. Honigfeld, once you determine that granulocytopenia has developed to the point where, according to your protocol, the drug should be discontinued, how long is it before there's a return to normal granulocytes in the peripheral blood after the discontinuance?

Dr. HONIGFELD. Anywhere from several days to a month. On average, about 2 weeks.

Mr. ROWLAND OF GEORGIA. So it is reversible fairly quickly, then, once the drug is discontinued; is that true?

Dr. HONIGFELD. Yes. The longest time for recovery we have seen is 4 weeks.

Mr. ROWLAND OF GEORGIA. Once you discontinue the drug on those people who have been helped by clozapine, who become symptom-free insofar as their schizophrenia is concerned, can you give me some idea of about how long before the symptoms of schizophrenia return, or how long are they abated?

Dr. HONIGFELD. That also is even more unpredictable than recovery of the white blood cells. Sometimes relapse may occur within a matter of days; sometimes weeks; sometimes months. But in almost every instance, relapse will be the outcome sooner or later.

Mr. ROWLAND OF GEORGIA. Is the relapse rate greater with those individuals who have taken clozapine as compared to those who are taking phenothiazines?

Dr. HONIGFELD. I think not. With phenothiazines in the long-term patient, the outcomes after, let's say, a year of discontinuation of therapy indicate that perhaps 90 percent of patients stopping phenothiazines will relapse over the course of that time. We think it's comparable with Clozaril as well.

Mr. ROWLAND OF GEORGIA. You think it's comparable then, so the relapse rate doesn't seem to be any greater on those patients taking clozapine as compared to those taking phenothiazines?

Dr. HONIGFELD. We think not. But my major observation is that most patients in this category of treatment-resistant schizophrenia will become symptomatic if they stop taking their medication sooner or later.

Mr. ROWLAND OF GEORGIA. Dr. Leber, what is the official position of the FDA with regard to the specific monitoring system, the Clozaril Patient Management System, that we have in place here?

Dr. LEBER. The monitoring system described in labeling is one of the conditions under which the drug was approved. However, I think there is considerable misunderstanding about what the intent of the agency was in approving Clozaril with that labeling. We were interested in the effects of the program i.e., CPMS rather than the specifics of the contractual arrangements under which Sandoz arranged for it to be carried out. Specifically, we were interested in the benefits the program provided to the patient.

Basically, as Dr. Honigfeld said, no blood, no drug. The reason for imposing such a condition is the concern that the case fatality rate of agranulocytosis is a direct function of the amount of time that elapses between the time the patient becomes agranulocytotic and the time which remedial medical efforts can be taken. So we wanted a system that would ensure that patients would not be "unmonitored" during treatment with Clozaril.

It is important to remember that this is a particularly "difficult to deal with" patient population, one that may not always act in their own best interest. Consequently, we felt, in this one case—and I don't know of any other in which we have attempted to do this—that it would be acceptable to endorse a management program that would condition the delivery of drug on the performance of weekly white counts.

This act does not set a precedent. Moreover critically, our approval of Clozaril's labeling is not an endorsement of the contractual arrangements that Sandoz has made with any specific provider. If Sandoz chooses—and it is their obligation to ensure that the drug is marketed under the labeling as it is currently worded—they could contract with other vendors—and they will give you their reasons why they will or will not do that, including the VA system—to deliver Clozaril under a monitoring system or to use a system that accomplishes, what the CPMS does; that is, conditions access to Clozaril on reliable monitoring of patients.

So, in our view, many alternatives to the particular contractual arrangements that now exist could be consistent with labeling and acceptable to us. What would not be acceptable under the current labeling would be for Sandoz to abolish or abandon a system of distribution that requires that weekly white counts be obtained on patients under treatment.

We have and will continue to make our position on this matter this clear to anyone who asks. Namely, our endorsement of "CPMS" is not a specific endorsement of a specific contractual arrangement that has been made by Sandoz.

Mr. ROWLAND OF GEORGIA. To be sure I understand exactly what you're saying, it is a requirement, if this drug is going to be used, that it has to be monitored with agranulocyte evaluation that is part of the system, but that does not necessarily have to be a contractual arrangement with a specific laboratory?

Dr. LEBER. Well, let me restate this because this may be a little tricky.

Sandoz has an obligation to ensure that their product will not be misbranded; that is, they have to distribute the product in accordance with the labeling that is approved. The current labeling was approved under the Act by virtue of the NDA approval. At this point, if Sandoz chooses not to distribute the drug, that would be legally acceptable. If they choose, they may distribute the drug through any vendor they want, provided that vendor provides the services specified in the labeling as written. That's acceptable too. Sandoz does not have to have a particular vendor identified i.e., named in labeling for example, I forget the name. Is it Caremark?

Mr. GRADY. Yes.

Dr. LEBER. They don't have to use Caremark, from our point of view. We never looked at that aspect of the CPMS. We were look-

ing at the form of the arrangement rather than the identity of the vendors.

Mr. ROWLAND OF GEORGIA. If my colleagues will permit, let me pursue this just a moment further.

Is Clozaril a more dangerous drug to human life than chemotherapeutic agents, immunosuppressives?

Dr. LEBER. I think, if you permit me not to answer that yes or no, that one has to consider the context in which you're asking the question. A patient receiving——

Mr. ROWLAND OF GEORGIA. I'm asking the question in the context of monitoring the drug that is used.

Dr. LEBER. I think the conditions and monitoring are critical to the answer. The patient receiving chemotherapy that suppresses the bone marrow is understood to be at risk immediately for the bone marrow suppresion that may follow and is monitored accordingly. In contrast, the seriously impaired schizophrenic patient is at risk over the entire time that he or she takes Clozaril. Under ordinary circumstances, monitoring over this lengthy interval will not be as intense or consistent with the patient on chemotherapy.

I can't say what the differential case fatality rate would be for agranulocytosis induced by a chemotherapeutic agent and that associated with Clozaril. We don't have that data in general, and we luckily don't have it with Clozaril in the United States, because no patient who has developed a granutocytosis on Clozaril died so far.

But, it seems to me logical that if early detection mitigates or militates against the rate of fatality, that patients undergoing chemotherapy are going to be monitored perhaps daily for their white counts, and if they get in trouble, there can be interventions made immediately. In contrast, a schizophrenic patient, an ambulatory one, may be wandering the streets of New York, living in the tunnels of Grand Central Station and not be subject to monitoring. Moreover, not everyone who gets Clozaril is going to respond positively. Remember, even though it is a breakthrough drug for some, it is a drug that has not helped others. It is critical for us to know that everybody who is at risk by being exposed to Clozaril will get timely white counts. You cannot rely on the fact that we can monitor people cooperating in their own care, who are cancer patients getting chemotherapy; they are not an apt model for the schizophrenic population that may not be responding ideally and may, in fact, not be cooperating in their own care. I think that is probably the critical nexus of the difference.

Mr. ROWLAND OF GEORGIA. Let me stop right there. I will come back for more questions.

I recognize the gentleman from Arizona.

Mr. STUMP. Thank you, Mr. Chairman.

Mr. Chairman, the Department of Veterans Affairs has been in the forefront of Clozaril issue for quite some time. They were able to provide the committee staff a very detailed briefing in January, and from the very beginning, the VA has taken an active role in the resolution of this issue and has done a superb job of advocating on behalf of veterans with schizophrenic disorders. In particular, Dr. Lehmann, the VA's Associate Director of Psychiatry, and Mrs. Louise Rodriguez of VA's Pharmacy Service, deserve recognition. I

would like to join with you in welcoming them and the others testifying today.

I have a couple of questions, Mr. Chairman, and then will submit some for the record. I know we're probably going to be short of time.

Mr. Grady, Dr. Reid of the American Psychiatric Association states in his testimony that clearly, Sandoz is not limited to utilizing Caremark as the sole provider of CPMS. What is your view on that?

Mr. GRADY. Our view, Congressman, is simply that we looked at other systems, that other potential providers of health care were unable or unwilling to make the capital investment necessary in developing a national system.

Even in Caremark's case, which is a large organization, they have had to hire 300 people and open 30-some offices to make this system operate in the best interests of patient safety. So while some people could do it on a local basis, very few, if any, were willing to incorporate a nationwide system.

Mr. STUMP. Are there any limitations in your contract with Caremark which would preclude you from approving the VA's Clozaril management system?

Mr. GRADY. Yes, there are. It is an exclusive contract at this point with Caremark. We are looking, however, Congressman, at potential pilot projects based on level of monitoring. We have discussed this with the VA and we have discussed it with other health care providers. We are willing to attempt to pilot project the Clozaril Patient Management System within other systems.

I think Dr. Leber said it correctly, and as Dr. Lehmann and Miss Rodriguez understand, that one of our reasons for rejecting the VA system is, on paper, many other organizations have a potential, workable system. But Sandoz maintains the responsibility for the accuracy and quality of those systems. So for me to hire 50 or 100 auditors to be on airplanes around the country, to make sure this institution did it and entered their data and somebody else did it, is far, far more expensive than the single, dedicated staff concerned with patient safety at Caremark. It's a complex issue.

Mr. STUMP. How much does the drug Clozaril cost without the cost of the Clozaril Patient Management System?

Mr. GRADY. For contractual reasons, I can't discuss the price of the drug. I can tell you this, because it has been at issue. Sandoz does not financially profit from the system itself. It is strictly a contractual basis for services, and Sandoz does not profit from the home health care delivery and blood testing part of the system.

Mr. ROWLAND OF GEORGIA. Would the gentleman yield on that point?

Mr. STUMP. Yes.

Mr. ROWLAND OF GEORGIA. Earlier I believe you stated that, in the United Kingdom, the monitoring system was separate from the drug itself. Can you tell us what the drug costs in the United Kingdom?

Mr. GRADY. I have seen the same reports. I think it's between $35 and $45 a week, in that range.

Mr. ROWLAND OF GEORGIA. Between $35 and $45 a week?

Mr. GRADY. Yes, sir.

Mr. ROWLAND OF GEORGIA. Thank you. I thank the gentleman for yielding.

Mr. STUMP. Dr. Lehmann, let me ask you a question, if I may.

Sandoz stated that the reason it insists on the Clozaril Patient Monitoring System is due to product liability issues. If Sandoz were to agree to allow the VA to apply its own monitoring systems, who would assume the liability for deaths as a result of agranulocytosis?

Dr. LEHMANN. Our proposal includes the VA assuming liability for all aspects of the distribution and monitoring of patients on clozapine, in the case of any therapeutic misadventures. Certainly, if in the case of a misadventure there was a problem with the actual product itself, with the clozapine itself, clearly that would be an area of the company's responsibility. But if we were allowed to assume, under our VA monitoring system proposal, control over distribution and monitoring, then logically we would assume liability for that.

Mr. STUMP. Would you describe your negotiations with Sandoz Corporation and the status of implementing the VA CPMS?

Dr. LEHMANN. Yes. When we recognized the imminent release of clozapine on to the U.S. market for February of 1990, we organized a VA Clozapine Task Force, made up of a number of clinician experts within VA who had had experience with clozapine, and others with experience in the treatment of chronic schizophrenia, cochaired by myself and Miss Rodriguez.

We formulated our VA clozapine monitoring system proposal in such a way that we would be able to at least match, if not better, the monitoring aspects of CPMS, which is a very thorough system. We added a number of unique features to it, features that would not have been found in any other system during the period of the field trials. So we believe that regarding comparability, the VA system could not be compared to any of the other systems, apart from CPMS, that existed during the field trials.

We have automated controls over the drug prescription that would lock out any potential for drug prescription if blood had not been drawn, or if the white blood count were seen to be declining, particularly into the dangerous range. Furthermore, this would involve a national risk management system whereby we would be able to track very closely any problems that patients were having, as well as any movements of patients.

Also, in recognition of Sandoz' appropriate concern with the rechallenged patient, it would be quite easy, as we have explained to Sandoz, for us to transmit any information about the patients, so that their monitoring system or any other national tracking system for clozapine patients would be intact.

Mr. STUMP. Mr. Chairman, if I may continue with Dr. Leber for one moment.

Dr. Leber, could FDA require Sandoz to relabel the Clozaril packaging?

Dr. LEBER. I think we could negotiate with them. It depends on what we were trying to secure. As you probably know, the law says the labeling cannot be false and misleading in any particular. If the labeling is deemed in some way to be misleading, I suppose we could persuade them to change aspects of it. We could not impose

something on the grounds that it had a beneficial economic impact because that is not part of our purview. We can, however, ask a sponsor to change something when we conclude that the product isn't safe for use under the labeling, or it is not effective in use under the labeling. But we specifically looked at these two issues in considering the original approval action, so it seems unlikely that we would now reach a different conclusion and find now that the distribution of Clozaril without such a system would be "safe for use", in the technical jargon of the law. Of course, I can't speak officially about something that the Agency might do in the future.

But it seems to me, given what I know about the people involved in our dicision-making and the basis for the judgments that have been made over the period of 8 or 9 years we have been assessing the risks of Clozaril, that our concerns about Clozaril, even recognizing that it has been shown to be superior to standard treatments persist. In particular, we have been and remain concerned that the distribution of Clozaril may extract a penalty, an enormous one, in terms of numbers of fatalities. It was this concern that convinced the agency that the CPMS was vital to the safe use of Clozaril and I do not think that we would back away from this judgment at the present time.

One aside. I'm less sanguine than Mr. Grady about the possibility of revising the distribution requirements on the basis of experience gained under the Clozaril Patient Management System, for one obvious reason, I believe. That is, if we have relatively few cases of agranulocytosis under the system—and Dr. Honigfeld told me moments before the hearing that they've already detected several in an early phase—we will still have no basis to judge how well an alternative system of distribution would work unless we did a comparative experiment. I'm not sure how that could be done at the moment.

So, as things now stand, we believe a monitoring system is essential to make the drug safe for use. We are willing to talk to Sandoz about modifying the precise requirements of the CPMS, but the essence of that system—no blood, no drug—I think is pretty much consistent with FDA policy at the present time.

Mr. STUMP. Thank you, Dr. Leber.

Thank you, Mr. Chairman, for allowing me all the time.

Mr. ROWLAND OF GEORGIA. Thank you.

Mr. Jontz.

Mr. JONTZ. No questions.

Mr. ROWLAND OF GEORGIA. Mr. Smith.

Mr. SMITH OF NEW JERSEY. Thank you, Mr. Chairman.

Dr. Lehmann, Dr. Honigfeld referenced some 18 patients who manifested some side effects, and I presume those side effects were largely mitigated because of that early detection. I wonder if you can tell us, in your view, is the VA system adequate to the rigors of that detection—and Mr. Grady or Dr. Honigfeld may want to respond to that—to try to compare what are the pluses and minuses of the two systems?

Dr. LEHMANN. We believe that the VA proposal would be able to adequately monitor for the side effects of agranulocytosis with the same and, in many cases, more rapid response than under CPMS. For example, patients coming into a VA clinic for clozapine, under

our system, could have their white blood counts, their blood drawn, as they come into the medical center, then they could go to the clinic for their psychotherapy treatment and contact would be with their psychiatrist and other clinicians. By the time they are ready for their prescription to be written or picked up, they might well have the white blood count back in hand for our clinicians to review.

Under CPMS, they have the obligation to send the specimen to their lab and there can be delays in terms of getting that report back if it were problematic. We could get our response in much more rapid time.

In addition, although we have focused our attention on granulocytopenia as the major life-threatening side effect of clozapine, which it is, there are other side effects from the use of clozapine, as there are with other medications including risk for seizures, and the incidence of tachycardia, increase in heart rate. We will, of course, in VA, be able to provide a comprehensive observation and monitoring of the patient's overall physical and mental status.

Mr. SMITH OF NEW JERSEY. Dr. Honigfeld.

Dr. HONIGFELD. Yes. We have some concerns and a great deal of interest in what the VA capacity is. I think a major factor for us in evaluating other alternative proposals is that we have field tested, and now have in actual commercial use, a program with a better than a 99 percent compliance rate. We know that patients are not falling between the cracks. This is not to imply that they would in the VA system. But I think any system, much as before we went commercial on February 5 with the Caremark system, we needed data to be absolutely certain that a high standard of patient safety could be attained, that no alternative can be evaluated strictly on paper. It has to be evaluated in terms of an actual proven track record of performance, and that is critical to us.

Other distinctions that we feel are important include the fact that the Caremark system that we have contractually put in place involves a treatment and a safety network staff that is 100 percent devoted to this activity only. There is no shared activity among Caremark staff. Their only job is looking after the safety of Clozaril patients. We have concerns about busy clinicians in other environments who may have multiple functions to serve, and are not yet certain as to what impact anything less than a fully dedicated staff would have on patient safety. So there are a number of unanswered questions.

Mr. SMITH OF NEW JERSEY. Is the management system employed by the British similar to or exactly the same as the Sandoz system?

Mr. GRADY. It's not exactly the same because, as you know, health care delivery systems vary by country. But the essence of the concepts of the Clozaril Patient Management System are included in the United Kingdom, the no blood, no drug philosophy.

Mr. SMITH OF NEW JERSEY. Mr. Grady, you testified, not unexpectedly, that Sandoz considers the potential human liability to be the overriding concern, and that is as it should be. But you also spoke to the legal liability.

I was wondering—and Mr. Stump asked a question along these lines, and maybe Dr. Lehmann would want to answer this—you say that the VA should assume total liability? But is that possible? I

mean, we all know that when lawsuits are brought before the court, those who feel they have been injured very often not just sue a Government agency but go after the producer, the manufacturer, perhaps even the inventor and father of the drug himself. I mean, all those are possibilities.

How does the VA ensure strict liability only for the VA?

Dr. LEHMANN. I would respond initially by saying even if VA uses clozapine under CPMS, for which Sandoz presumably would have primary liability, I strongly suspect that if there were therapeutic misadventures, VA could be sued in that situation as well. I can only say that our proposal was that we clearly would be willing to assume a liability for our system due to the fact we were using our system instead of CPMS, and to that extent, Sandoz might have some form of protection from liability because it was not their CPMS that was being used in the situation.

Mr. SMITH OF NEW JERSEY. For the record, if the attorneys from the VA could elaborate on that, I think that would be most helpful, to give us some insights into——

(Subsequently the VA submitted the following additional response:)

By way of clarification, the issue of Sandoz' liability stems from the language of the package insert labeling which was approved by the Food and Drug Administration (FDA). As approved, the label states that "Clozaril is available only through the Clozaril Patient Management System, a program that combines white blood cell testing, patient monitoring, pharmacy, and drug distribution services, all linked to compliance with required safety monitoring." (It is noteworthy that the drug's manufacturer proposed (this language, subsequently approved by FDA.) In a later clarification, the FDA emphasized that it interprets the reference to the Clozaril Patient Management System (CPMS) as a reference to any scheme that the manufacturer chooses to use that establishes weekly white blood cell testing and patient monitoring as the prerequisites for dispensing continued supplies of the drug to the patient. The FDA has emphasized, though, that the manufacturer, Sandoz Pharmaceuticals Corp., would remain responsible for assuring that any system through which it distributed the drug assured that drug dispensing was conditioned on weekly testing and monitoring. Sandoz attorneys thus maintain that if the company permits the use of a provider's monitoring system rather than its own, it becomes exposed to liability in the event of a patient's death or illness due to negligence in the administration of that alternative system. Such joint and several liability, they maintain, would be based on a finding that Sandoz was negligent in failing to exercise due care in approving the use of a provider's monitoring system.

In fact, VA cannot fully indemnify Sandoz under the Federal Tort Claims Act for liability in connection with VA's operation of its monitoring system. VA could not indemnify Sandoz under the Act for punitive damages for example. In accordance with the Act, it could at most indemnify Sandoz with respect to compensatory damages as determined under and to the extent permitted under the Act's provisions.

It is noteworthy, however, as regards the VA's monitoring system that it is widely regarded as superior to CPMS. And at a July 26, 1990 meeting with major professional associations, FDA officials acknowledged that VA's monitoring system fully met FDA's requirements.

Mr. GRADY. And we would be most welcome to, also. What is true is that the VA and we and any practitioner is always liable for their own malfeasance in the use of anything. The fact is that nobody can take away all of our liability, except perhaps the Congress of the United States. If all of you would like to consider exempting us from liability concerning this drug, we certainly would be willing to entertain that.

Mr. SMITH OF NEW JERSEY. If I could ask one additional question, Mr. Chairman, very briefly, and this would be to Dr. Lehmann.

Does the VA have the resources necessary to treat all veterans for whom Clozaril is clinically indicated?

Dr. LEHMANN. At the current cost of $9,000 per patient per year, a conservative estimate of the number of patients in the system currently who might be candidates for clozapine was made at about 2,000 individuals. This roughly approximates the number of individuals who during fiscal year 1989 were hospitalized for 6 months or more for schizophrenia. We suspect that that number might be too conservative an estimate.

As has been mentioned, there are other individuals who do not respond optimally to current therapeutic and pharmaco-therapeutic agents. About 27,000 individuals were admitted for a primary diagnosis of schizophrenia in fiscal year 1989. If we would estimate, as certain studies have, that about 30 percent of schizophrenics do not respond optimally to medication, that would be about 9,000 individuals who don't respond optimally. The field studies of clozapine suggest that about 40 percent of the individuals who are treatment-resistant, who are tried on clozapine, have some kind of positive response, 40 percent of 9,000 being about 3,600, the cost to the VA might be as much as $32 million for the drug alone.

Because these patients are spread throughout our nationwide system, with regard to cost savings for those individuals, certainly would anticipate a lower percentage, perhaps only 10 percent of responders could be discharged from the hospital. This would probably not result in an overwhelming cost savings to VA as a system because cost savings for inpatient care come from the ability to close beds, to close units. With these individuals spread throughout our system, we suspect that there would be relatively little savings from closing beds even if these individuals were capable of being discharged from our system. So it would be a significant cost burden for the drug alone.

Mr. SMITH OF NEW JERSEY. Thank you for your answers, and thanks to the entire panel.

Mr. ROWLAND OF GEORGIA. Thank you. You have been at the witness table a long time and I apologize for that. But let me ask a couple more questions, if I may.

Dr. Leber, are you familiar with the proposal of the VA to monitor the side effects of Clozaril?

Dr. LEBER. Only in a very broad way. I was given a copy of the document this morning by Dr. Lehmann. So we haven't had an official——

Mr. ROWLAND OF GEORGIA. It has not been submitted to FDA in any form prior to today?

Dr. LEBER. Just hours ago to me and I have not reviewed it in detail. But in a general sort of way, the outline of the plan would seem to meet our interpretation of what a management system must be, if that's what you're getting at.

The point I still want to come back to is the responsibility for the marketing of the drug under the labeling does not lie with us but primarily with Sandoz. That's the point.

Mr. ROWLAND OF GEORGIA. I guess the question that I have is whether or not we're going to be able to afford this drug in the VA. If we look at the cost of the drug, if you see what it has cost in the U.K., and even taking the highest cost, it would be $2,000 a year.

So we're talking about $7,000 a year to monitor that. But I understand the cost of the drug would not be nearly that much in all likelihood.

I want to encourage those principals that are concerned with this issue to look closely at what the VA is proposing and make a determination as to whether or not the drug could be made available to the Department of Veterans Affairs for use on veterans and whether or not the VA system of monitoring will be satisfactory to meet the requirements. So I would encourage you to look at that.

I guess you set up a system that is pretty fail-safe, at least that's what you hope that you've done. I don't guess any system is really fail-safe. Maybe you're familiar with this incident—I just learned about it—in northwest Georgia. This came to our attention through the Georgia Medicaid Formulary Committee.

There was a patient that lived about two hours away by automobile who was given the drug. Caremark had contracted with the nurse who worked in the doctor's office on her own time to draw the blood to submit for evaluation. The question was asked, what would happen if for some reason there was maybe car trouble or illness or whatever and you weren't able to get the drug, you weren't able to be monitored, and the family replied, well, we're not too worried about that because they always mail more than the required dose and we've got a "grocery bag full" of the drug here, so we're not really concerned about that.

I guess any system is not going to work perfectly. Are you aware of what——

Mr. GRADY. I would be unaware of any particular circumstances. We do know there have been many rumors about those kinds of things happening.

I do want to say, however, that every patient is given a few days' extra medication in case of emergency and/or snowstorms, so that a patient does not relapse. They are not given enough to pose a potential danger to themselves. For example, I don't know that the physician or pharmacist always has the capability of driving two hours away. That's the service we're attempting to provide. So there is a minimal but adequate supply of extra drug given for those exact circumstances.

Mr. ROWLAND OF GEORGIA. I guess if every patient is given a few extra days over a period of time, they could really accumulate a lot of that drug. They might decide, for whatever reason, I just don't think I'll go back and get monitored. That seems to me to really blow a hole in the system.

Mr. GRADY. At least, Congressman, it stops that very same thing. If it happened in the general outpatient setting today, nobody would know it and no blood would be tested, at least at some point.

Mr. ROWLAND OF GEORGIA. We talked about the irresponsibility of people who are schizophrenic on an outpatient basis, and I can certainly understand that they may not come back in. But what about those people who are treated on an inpatient basis where they're going to be monitored? You know they're there. I guess that's what we're talking about to a significant degree in the VA. Those patients are going to be there. They are going to be monitored. You know they are because you have them as inpatients.

The system that you put in place, would that be not as rigorous on inpatients as outpatients, for example, in compliance?

Mr. GRADY. We don't know. I think as Dr. Honigfeld mentioned, in the research trials, and one of the reasons for attempting—and I agree with you that we may never achieve "fail-safe"—is that under strict research protocol conditions, the weekly monitoring rate fell below 70 percent even in our research clinical trials. From our point of view, that's unacceptable with the potential patient dangers that are involved.

I believe most could monitor the inpatient setting and, of course, we would require just to know that that was done. But not all inpatients remain inpatients. The minute a patient leaves that particular institution and becomes a mobile patient traveling around the country, even in the community, then the documentation and the records are lost.

Mr. ROWLAND OF GEORGIA. Mr. Stump.

Mr. STUMP. Thank you, Mr. Chairman.

Mr. Grady, I would like to follow up for a moment on the question I asked you a while ago about the cost of the medication without the monitoring system. I believe you stated that because of a contractual agreement with, I assume, Caremark—is that correct?

Mr. GRADY. That's true. Yes, Caremark and Baxter, which is their parent company, yes.

Mr. STUMP. If they had no objection—and maybe you don't know whether they do or not—to disclosing the cost of that, would you have any objection then to follow up on——

Mr. GRADY. As a matter of fact, Mr. Congressman, we would have to have their permission. But we had already, before we knew about this hearing, planned to have several congressional contacts concerning that entire pricing issue, yes.

Mr. STUMP. I didn't quite understand your answer.

Mr. GRADY. What I mean is that our Washington person has established some appointments in just a few weeks to discuss those very issues here in Washington.

Mr. STUMP. Mr. Chairman, I would like to follow this up, if I may, with some written questions for the record, if you would, Mr. Grady.

Thank you.

Mr. ROWLAND OF GEORGIA. Thank you very much. I really apologize for keeping you at the witness table for so long. I appreciate all of you being here very much.

The next panel is Dr. John Gans, who is Chief Executive Officer of the American Pharmaceutical Association; Dr. William Reid, Medical Director for the Texas Department of Mental Health and Mental Retardation, American Psychiatric Association; and Dr. Kenneth Klauck, Association of VA Chief Psychologists and American Psychological Association.

Thank you very much for being here this morning. Dr. Gans, you are accompanied by Dr. Webb?

Mr. GANS. Yes, Dr. Edwin Webb of our staff.

Mr. ROWLAND OF GEORGIA. Thank you very much. We'll ask you to proceed in your own manner, and please try to limit your remarks to 5 minutes.

STATEMENT OF JOHN GANS, CHIEF EXECUTIVE OFFICER, AMERICAN PHARMACEUTICAL ASSOCIATION; ACCOMPANIED BY C. EDWIN WEBB, DIRECTOR, PROFESSIONAL AFFAIRS AND POLICY

Dr. GANS. Thank you, Mr. Chairman, for the opportunity to appear before the subcommittee today. We commend you and the subcommittee for holding these hearings on two issues of deep concern to the Nation's veterans—the restricted distribution system for the new anti-schizophrena drug clozapine, and the issue of post-traumatic stress disorder. My comments today, however, will be focused on the clozapine issue.

The American Pharmaceutical Association is deeply troubled by the events surrounding the establishment by its manufacturer of a restricted distribution system for the drug clozapine. We are firm in our resolve that this system be dismantled in order that patients, including the Nation's veterans, their pharmacists and physicians, will be able to better utilize this therapeutic advance in the treatment of schizophrenia.

At the outset, let me acknowledge the important work that has been done on this issue by the Department of Pharmacy Services within the Department of Veterans Affairs. It has been our pleasure at APhA to be in close communication with the VA pharmacy central staff and to share information and efforts to resolve this critical problem.

APhA's position on the restricted distribution system for clozapine, known by the service-marked title of Clozaril Patient Management System, CPMS, is clear and unequivocal. We believe that the system is clinically, scientifically and economically unjustified. We have appended to our written testimony additional materials which time does not allow me to present at this hearing. But I do encourage the subcommittee's review of this material to gain additional insight into APhA's position.

Briefly, APhA opposes restricted distribution of FDA-approved drug products because such actions preclude the full involvement of pharmacists in patient care. The current situation with clozapine/CPMS is a prime example of the problems created with such a system. Focusing on a single drug, and specifically monitoring for only one side effect of that one drug, CPMS results in pharmacy care that is fragmented across multiple pharmacy care providers, is isolated from other parts of the patient's pharmacy and medical care, and is unnecessarily expensive due to duplication of resources and procedures commonly available to patients.

Frankly, can we afford systems that monitor just for one drug and, more specifically, for only one side effect of that drug?

Specifically, APhA opposes CPMS because, number one, the system interferes with established relationships of pharmacists, patients and physicians; number two, the incidence of clozapine-induced agranulocytosis is insufficiently different from, and in some cases is less than, other widely available medications which may cause this problem. These medications are currently managed effectively by pharmacists and physicians in all types of practice settings in carrying out their patient care responsibilities.

Number three, other manufacturers of products with severe adverse effects have worked effectively with pharmacists and physicians to prevent drug-related problems, rather than circumventing them in the system.

Next, the FDA did not require CPMS as a condition for drug approval. Lastly, CPMS needlessly increases the cost of clozapine therapy. At approximately $9,000 per patient per year, CPMS results in needless duplication of resources for many patients who already receive pharmacy, laboratory and other care and services within the current system.

I would also like to point out that two major groups that would be affected by this system, the VA and the Medicaid program are both financially strapped for resources at this point.

As you have heard from the VA personnel and others, our profession has extended many offers to Sandoz to develop mutually agreeable solutions to this dilemma. In fact, the VA's suggested system for monitoring clozapine, which was twice proposed to Sandoz and twice rejected, would, in our view, have offered equal if not greater monitoring safety that that offered by CPMS. We also know that there are many pharmacists and pharmacy care providers currently working within the mental health community which can offer the same or an even greater degree of monitoring safety. In fact, Mr. Chairman, in your own State, clinical pharmacists have been hired by the Georgia Mental Health Care system to provide such services.

We therefore base our opposition squarely on the issue of Sandoz' circumvention of the professional practice capabilities of pharmacists and physicians in the management of complex and potentially hazardous drug therapies. We believe that this sets a precedent which ill-serves patients and providers and the health care system in general. While we strongly support the many ongoing efforts to analyze the economic, antitrust and other issues associated with CPMS, it is this usurpation of professional practice prerogatives that troubles our profession most deeply.

I would also point out our substantial concerns regarding the role of the Food and Drug Administration in this matter. In approving the current labeling for clozapine, FDA as injected itself directly into the regulation of the practice of pharmacy and medicine. We believe FDA's decision to specifically require weekly white blood cell analyses, rather than relying on the clinical judgments of health care providers, is beyond the agency's statutory authority. Officials of APhA, FDA and the American Medical Association will be meeting next month to seek clarification of this issue and its impact on our practices.

Discussions between APhA and FDA staffs, however, have been helpful in achieving some critical clarifications, which you've heard described earlier this morning.

In short, APhA believes that there are many pharmacists and pharmacy systems capable, willing and eager to provide effective clozapine therapy and monitoring services to patients in a more cost-effective manner than the monopolistic Caremark/Sandoz system. We will continue our efforts to achieve this opportunity for our profession, for our patients, and sincerely appreciate the subcommittee's efforts in bringing attention to this issue.

I would be happy to answer any questions you may have, Mr. Chairman.

[The prepared statement of John Gans, w/attachment, appears at p. 92.]

Mr. ROWLAND OF GEORGIA. Thank you, Dr. Gans. We will go ahead and hear from the rest of the members of the panel and then come back.

Dr. Reid.

STATEMENT OF WILLIAM H. REID, M.D., MEDICAL DIRECTOR, TEXAS DEPARTMENT OF MENTAL HEALTH AND MENTAL RETARDATION; APPEARING ON BEHALF OF THE AMERICAN PSYCHIATRIC ASSOCIATION

Dr. REID. Mr. Chairman, members of the subcommittee, I am Dr. William H. Reid, Medical Director of the Texas Department of Mental Health and Mental Retardation, and Liaison for MHMR Affairs for the University of Texas system.

I am appearing on behalf of the American Psychiatric Association, a medical specialty society representing over 36,000 psychiatrists nationwide. Our comments today focus on mental health funding and workload, the impact of Clozarile medication costs on DVA medical services, and the DVA's ability to help veterans suffering from post-traumatic stress disorder.

The DVA mental health workload has increased dramatically over the past 5 years. In spite of this increase, overall inpatient direct care dollars that are distributed to DVA psychiatry have decreased since 1984.

The effect of implementing the resource allocation methodology in psychiatry has been to increase outpatient care at the expense of an increasing inpatient workload. Although patients should be treated in alternative settings when possible, there are many who require inpatient treatment. The DVA's ability to address the needs of all psychiatric patients is being severely hampered.

In addition, DVA psychiatry must now address the extraordinary cost of the new antipsychotic medication Clozaril. Clozaril represents a breakthrough in the treatment of patients with schizophrenia. As you know, schizophrenia is a severe, chronic, lifelong illness, usually beginning early in adulthood, suffered by over two million Americans. The VA had more than 71,000 inpatient admissions for schizophrenic patients in fiscal 1988.

We share the great concern of State policymakers, physicians, other professionals and health care administrators about the very expensive, medically unwise, and unfair conditions under which Clozaril is being marketed. The only way American patients can get the Clozaril they need is by also purchasing a package of nonpatented services, the Sandoz CPMS, every week.

The most obvious problem associated with Sandoz' mandatory package is its cost—almost $9,000 per year. In England, the drug and similar services cost about $1,500. This six-fold difference appears to reflect exorbitant charges for simple, albeit important, blood drawing, blood counts, and recordkeeping.

Sandoz' defends its charges by predicting savings from decreased inpatient hospital care. However, at least four-fifths of Clozaril-eli-

gible patients are not in hospitals. Further, their predictions do not include necessary outpatient medical monitoring and psychosocial rehabilitation for patients long outside society's mainstream.

If forced to use the Sandoz sole-source protocol, the VA will not be able to treat most of its patients who need Clozaril. Yet, when the DVA proposed a less expensive monitoring system, equal or superior to the Sandoz program in every way, it was flatly rejected by the company. Many severely disabled people will thus be denied that which, for now anyway, is their only hope.

As one advocacy group member recently protested, "It's the first drug ever that you can't get through a doctor, you can't get through a hospital, you can't get through a pharmacy. Where will this lead?"

Let me now turn to the need for expansion of PTSD related services. The findings of the National Vietnam Veterans Readjustment Study overwhelmingly support the contention of many practitioners that there is a substantial unmet mental health need among veterans suffering from this disorder. Both psychiatric and nonpsychiatric hospitalization rates strongly indicate that veterans with PTSD require the full array of VA mental health services.

H.R. 3037 would authorize expansion of PTSD services. However, much of the new funding would be used to expand Vet Center programs and fund contracts with private facilities and therapists. We feel this money would be more efficiently spent for expansion of DVA's well-proved, specially-trained PTSD treatment teams and inpatient PTSD units.

Mr. Chairman, new resources must be allocated and old ones reallocated if our patients are to receive the quality of care to which they are entitled. We greatly appreciate your efforts and those of the subcommittee, and I thank you for this opportunity to testify.

[The prepared statement of Dr. William Reid appears at p. 109.]

Mr. ROWLAND OF GEORGIA. Thank you very much.

We have a vote on the House floor. I think we will recess for the length of time that's necessary for us to go over and vote. We will stand in recess until we can go vote. We'll be back shortly.

[Whereupon, the subcommittee was in recess.]

Mr. ROWLAND OF GEORGIA. The subcommittee will now resume.

Dr. Klauck, we will hear from you at this time.

STATEMENT OF KENNETH A. KLAUCK, CHIEF OF PSYCHOLOGY SERVICES, CLEMENT J. ZABLOCKI DVA MEDICAL CENTER; APPEARING ON BEHALF OF THE AMERICAN PSYCHOLOGICAL ASSOCIATION AND THE ASSOCIATION OF VA CHIEF PSYCHOLOGISTS

Dr. KLAUCK. Good morning, Mr. Chairman. I am Kenneth A. Klauck, Chief of Psychology Services at the Clement J. Zablocki VA Medical Center in Milwaukee. I am testifying today on behalf of the 100,000 members of the American Psychological Association and the Association of VA Chief Psychologists, of which I am the immediate past president. I have over 25 years of experience with the VA. I am a service-connected veteran and a life member of many of the veterans' organizations which will appear later. I have also served as president of the APA Division of Psychology in

Public Service and I am currently the APA representative for that division.

Mr. Chairman and members of the subcommittee, on behalf of the APA and the Association of VA Chief Psychologists, I wish to thank you for giving me the opportunity to testify today.

We are providing comprehensive, effective, mental health services to veterans. I also believe the VA model for the delivery of mental health services is exemplary, given its tremendous demand for mental health care. Mental health professionals are attempting to meet the needs. However, it seems clear that more resources need to be allocated.

We support the expansion of the VA Homeless and Chronic Mentally Ill program. This program, implemented in 1987, has an excellent track record, and we support efforts to extend the program and remove its designation as a pilot project.

The Compensated Work Therapy program, CWT, is a program which I believe holds great potential for aiding our efforts to care for veterans suffering from mental disorders. The Compensated Work Therapy program provides numerous therapeutic benefits to veterans relating to job skills and training. CWT is a valuable tool in treating mental illness.

Mr. Chairman, it is becoming quite clear that the most cost-efficient and effective way of treating all persons with mental disorders is to tailor services to individual need. To do so requires access to a range of options for providing a continuum of mental health care. Inpatient care alone is not sufficient. Often individuals need less intensive aftercare to ensure continued recovery and adjustment. Access to care and an appropriate continuum of care by highly qualified health care providers is necessary to effectively treat the mental health problems of veterans.

This concept of providing a continuum of mental health care services is especially important in the treatment of veterans suffering from post-traumatic stress disorder. Clearly, the Department of Veterans Affairs has a particular responsibility for the care of veterans with PTSD.

While much is being done within the VA, we believe that more needs to be done. It is appropriate to look at veterans receipt of PTSD services. PTSD is, in the most basic sense, a service-connected condition, and yet veterans have limited access to VA treatment services because they have not been adjudicated as service-connected.

We believe provision should be made for the treatment of PTSD on a priority basis and for expedited access to assessment for PTSD.

Beyond the issue of a veteran's eligibility for treatment services, the concept of a comprehensive continuum of care is essential to ensure that mental health care is tailored to the individual needs of the veteran, achieves desired results, and is cost effective.

Representative Jontz' bill recognizes the need for a continuum of mental health care services for PTSD treatment. We applaud this effort to take a comprehensive approach to expanding PTSD services. We are generally supportive of any needed expansion of the number of specialized inpatient units and Vet Centers. However, we wish to emphasize that new Vet Centers or specialized inpatient

units should only be expanded to areas where services are lacking and the need has been demonstrated.

It is important to note that PTSD is often accompanied by the diagnosis of severe alcohol or substance abuse. To this end, we encourage the creation of new PTSD substance abuse programs and the sharing of DVA staff and resources to ensure Vet Centers have access to these programs.

In the spirit of providing a continuum of mental health care for PTSD treatment, Representative Jontz has proposed a pilot program to contract for community-based PTSD treatment and rehabilitative services. While we support any initiative to test new ways to address the treatment needs, we are concerned that such initiatives may divert already scarce DVA resources to the detriment of existing programs.

Finally, we are generally supportive of the creation of additional group to advise on PTSD issues. We support additional PTSD research. The concept of providing a continuum of care with multimodal treatment services has been supported and advanced by the Director of the Mental Health Behavioral Science Service, Dr. Errera. We believe Dr. Ererra's approach to providing a flexible continuum of care for veterans with mental health problems offers a good working model for expansion. In addition, I would like to stress that the additional programs not operate to divert already scarce funds.

In summary, I believe there are a number of programs within the mental health care system which bring hope and promise to veterans suffering from a variety of serious mental disorders, including PTSD. The APA and the Association of Chief Psychologists pledge their continued support and cooperation in efforts to extend and refine such programs and to ensure the development of advances in treating PTSD and other mental health problems.

I thank you for giving us this opportunity to testify, and I would be happy to answer any questions you and the members of the subcommittee may have.

[The prepared statement of Kenneth Klauck appears at p. 120.]

Mr. ROWLAND OF GEORGIA. Thank you, Dr. Klauck.

Mr. Stump.

Mr. STUMP. Thank you, Mr. Chairman. I do have a couple of questions that I would like to submit to Dr. Gans to answer for the record, if he would, please. Other than that, because of the time, I will not ask any more.

Thank you, gentlemen, for appearing and taking the time. We apologize for the vote delay.

Mr. ROWLAND OF GEORGIA. Mr. Jontz.

Mr. JONTZ. Thank you, Mr. Chairman.

I don't have any lengthy questions to ask, but I did want to raise an issue with Dr. Reid that he covered in his testimony. Dr. Reid, I certainly don't disagree with your recommendation that we should be expanding the number of clinical treatment teams. The figures I have is that the cost of the PCTs are about $230,000 per unit; is that right?

Dr. REID. I'm not sure, sir.

Mr. JONTZ. That compares to the cost of Vet Center expansion of $209,000 percenter, and inpatient units an average of $510,000 per-

center. And, of course, the contract care is really designed to provide care in settings where veterans don't have access to either inpatient or Vet Center services, probably, in most cases.

Do you think we're proposing too much in terms of Vet Center expansion, or do you think we ought to be able to do the things that are in our legislation and also expand the PCTs as the DVA apparently is planning to do?

Dr. REID. I believe the American Psychiatric Association is quite prepared to vigorously support efforts to increase veterans funding in these areas. I don't know, because of my inexperience in some of these areas, the exact amounts of money involved, et cetera.

I do know that the ability to serve the breadth of presentation and severities of PTSD is quite important and that the ability to offer highly specialized care for many of these individuals is also important. I don't know where the balances should be struck. I think the APA would be happy to respond for the record, if you wish.

Mr. JONTZ. Thank you. I think those are all the questions I have.

Mr. ROWLAND OF GEORGIA. I have just a couple of questions.

Let me ask you, Dr. Reid, do you have any idea about how many PTSD patients would benefit from Clozaril?

Dr. REID. The disorder PTSD is not, in itself, applicable to Clozaril. However, I think it's fair to say that there is significant overlap between the disorders known as schizophrenia and PTSD. The exact numbers I would not be able to say, sir.

Mr. ROWLAND OF GEORGIA. That's really what I was asking. How many PTSD patients are schizophrenic who may benefit from the drug?

Dr. REID. I don't know. I know that there is a significant overlap, but I'm not sure.

Mr. ROWLAND OF GEORGIA. It really wasn't a fair question.

Well, I take it, Dr. Reid, and Dr. Gans, that the American Pharmaceutical Association and the American Psychiatric Association do not feel this so-called system is necessary in the prescribing of Clozaril, that monitoring of the side effects could be done outside of this system, and that there may be many people who could benefit from this drug who cannot get it because of the way it is now structured?

Dr. REID. Yes, sir, that's accurate to say. Speaking for American psychiatry, we are quite certain that there are a variety of ways to skin this cat. It is, however, very important—and I do not disagree with the FDA's position and Sandoz' position—that monitoring is important and necessary.

However, one of the things you haven't heard today is that since we found that monitoring was necessary—that is, the past four or five or 6 years—there have been very few deaths worldwide related to Sandoz-produced Clozaril or clozapine. This number is on the order of zero to three per year.

Now, that takes into account several things. One is that in some areas it's not a popular drug. However, in other areas of the world, it clearly is a popular drug. The British monitoring system is institutionalized. However, the monitoring system in many other countries is not institutionalized. Physicians and health care programs simply know that they have to monitor it.

We feel that it can be adequately done in a variety of ways, and we would certainly like some choices. Speaking for the public sector, in which I work, and for which I have probably 25,000 eligible patients in the State of Texas, which we either fund or treat, we would like a few choices as to how we do that.

Dr. GANS. When you phrased your question, you used the term "side effects". The clear thing in the system is that they this "system" only monitors for one side effect, and that is agranulocytosis. It does not monitor for cardiac toxicity. That is supposedly left to somebody else. Our feeling is that physicians and pharmacists must monitor the whole patient.

If you look back historically—and I understand, Mr. Rowland, that you're a physician, a general practitioner—you probably prescribed Chloromycetin in your practice. That was a drug that caused agranulocytosis, and it was a serious problem. When we identified it, we monitored patients for it and we made sure the patients understood the problems.

Now, when you hear that patients who would use clozapine are unreliable, that's true. But that's not a positive outcome of therapy. If you put somebody on Clozaril and they're wandering around New York in the alleys, I don't think that's the outcome of therapy that we want.

I have seen patients that have been treated with Clozaril that are now functional citizens. They hold jobs and I think they can be part of a monitoring system. But what is needed is a system that monitors all drugs, as well as Clozaril, and that's what professionally-trained physicians and pharmacists are responsible for doing.

Mr. ROWLAND OF GEORGIA. Do you feel that chloramphenical is just as dangerous as the drug that we have under discussion here today?

Dr. GANS. I can't say that because I don't know the data, but I know that when agranulocytosis was first identified, it was very serious and it was pretty widespread. Then people began to limit the use of the drug. This problem was probably identified more than 20 years ago. But certainly, the antineoplastics, the anti-cancer drugs, cause more agranulocytosis than Clozaril, and the patients are appropriately monitored by the physicians and pharmacists in the system.

Mr. ROWLAND OF GEORGIA. Let me ask one other question. Dr. Reid, you mentioned zero to three deaths per year worldwide using Clozaril. Do you have any idea how many deaths worldwide there may have been related to phenothiazine or other psychotropic drugs?

Dr. REID. It would only be a broad idea, Congressman. Those deaths, by the way, the ones that I mentioned, zero to three, are for Sandoz-produced Clozaril. There are companies elsewhere in the world—in Russia, for example—that produce clozapine as well.

The source of deaths or serious morbidity are from phenothiazines—Tardive-dyskinesia doesn't kill folks, but it sure makes things miserable for a few. The neuromuscular malignant syndromes with phenothiazines are very significant. In terms of raw numbers, it's clearly more. In terms of proportion, it's probably less. However, with a reasonable monitoring system, most of us feel

Clozaril is safer than the other drugs, particularly because of the lack of problem with tardive-dyskinesia, so far as we know.

Folks haven't mentioned very much about seizures, by the way. For many people, this is a greater concern.

Mr. ROWLAND OF GEORGIA. You mentioned other side effects. We've been talking about granulocytopenia and agranulocytosis as the thing that is monitored. These several other side effects, are they just as life-threatening in some instances as what we're monitoring for here?

Dr. REID. There may be isolated instances in which that's the case. Certainly having a seizure at the wrong time can be life-threatening. Across the board, the agranulocytosis is the one that one can monitor for. It's one that we certainly can deal with. Seizures are a little less predictable.

Mr. ROWLAND OF GEORGIA. You mentioned cardiac toxicity, Dr. Gans.

Dr. GANS. Yes, sir. I have been told there was one death due to cardiac toxicity in a patient on clozapine. I think tachycardia is the major initial symptom that the patients get. Again, they're not monitored for this.

Mr. ROWLAND OF GEORGIA. Are there any additional questions or comments?

Dr. GANS. Mr. Chairman, in the system proposed by the VA, as I understand it, patients would be monitored for all of those side effects. Therefore, I think the VA system would be superior to the Sandoz system, because the VA would look at not only agranulocytosis but they would look at the patient entirely and at the other drugs the patient was on. I think that would be true of all pharmacy practices.

Mr. ROWLAND OF GEORGIA. I asked this morning that Sandoz and the FDA and the VA look at what the VA is proposing to see whether or not that would be acceptable under the requirements the FDA feels are appropriate.

Gentlemen, thank you very much for being here.

The next panel is Dr. Daniel H. Winship, Assistant Deputy Chief Medical Director for Operations, Department of Veterans Affairs; Dr. Paul Errera, Director, Mental Health and Behavioral Service; Dr. Arthur S. Blank, Jr, Director, Readjustment Counseling Service; and Mr. Ralph J. Ibson, Deputy Assistant General Counsel.

Gentlemen, thank you very much for being here. Dr. Winship, we will start with you, and ask each of you to limit your statements to 5 minutes.

STATEMENT OF DANIEL H. WINSHIP, M.D., ASSOCIATE DEPUTY CHIEF MEDICAL DIRECTOR, DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY PAUL ERRERA, M.D., DIRECTOR, MENTAL HEALTH AND BEHAVIORAL SERVICE; ARTHUR S. BLANK, M.D., DIRECTOR, READJUSTMENT COUNSELING SERVICE; AND RALPH J. IBSON, ESQ., DEPUTY ASSISTANT GENERAL COUNSEL

Dr. WINSHIP. Thank you, Mr. Chairman, members of the subcommittee. We are pleased to be here this morning to discuss VA's mental health services.

This subject raises some important issues and we welcome the opportunity to share in the debate. Among these issues are whether VA has the capability of meeting the needs of veterans who are psychologically scarred by combat or other profound distress or stress, and whether VA has sufficient legal authority to provide needed services.

VA and other health care systems nationwide also face an unprecedented and, in our view, untenable problem in attempting to simply purchase a recently marketed drug, Clozaril, which we've been discussing so far this morning. This drug, of course, would hold promise for helping treat the most intractable of our schizophrenic patients.

I believe I will skip over any comments about Clozaril. There are substantial comments in my testimony on that which I have offered for the record. But I would like to turn my attention to PTSD.

Just as the VA has, in our view, been a leader in confronting the issues posed by Clozaril's marketing, we have led the country in the development of clinical models to treat PTSD and in enlarging the health care community's understanding of that disorder. Currently, the VA's continuum of care for PTSD includes intensive inpatient care in 20 specialized inpatient PTSD units, specialized outpatient care with 44 PTSD clinical teams, and readjustment counseling, rehabilitation and treatment services through 196 Vet Centers.

Weighing the competing demands for resources and the base from which we started just a few years ago, the Department has made considerable progress in developing a sound health care infrastructure for PTSD care and conducting continuing medical education to meet veterans' needs.

As an aside, Mr. Chairman, and speaking of competing demands for health care resources, it has been our collective experience at the VA that this competition is increasingly stiff. Under tight budget constraints, when we try to put resource emphasis on a high priority mode of care, we end up taking from other existing programs. This will continue to happen unless Congress gives VA the commensurate dollars to support the new program emphasis.

Finally, Mr. Chairman, the full text of my statement outlines VA's position on H.R. 3037 and our objections to its enactment. We certainly share the goals reflected in the bill, but our concern is that Congress may not be willing to fund its expensive provisions.

This completes my verbal testimony. My colleagues and I would be pleased to respond to any questions.

[The prepared statement of Dr. Daniel Winship appears at p. 128.]

Mr. ROWLAND OF GEORGIA. Mr. Stump.

Mr. STUMP. Mr. Chairman, I have some questions, but I would like to submit them for the record, if that's all right, for Dr. Winship, because of the time constraints.

Mr. ROWLAND OF GEORGIA. Mr. Jontz.

Mr. JONTZ. Thank you, Mr. Chairman.

Dr. Winship, I certainly do appreciate what the VA has done to respond to the problem, and I don't, in proposing this legislation, seek to diminish in any way the good work that is going on now.

But I do have some questions for you about your particular position in some areas.

You have noted that the VA has adopted a number of the Director's Special Committee on PTSD's recommendations that they have furnished in their six annual reports.

Dr. WINSHIP. Yes, sir.

Mr. JONTZ. I read from Dr. Falcon's testimony: "The Special Committee continues to recommend that in order to meet VA's priority to provide quality care in a timely manner to veterans suffering from service-related disabilities, that a SIPU should be established in each State."

For how long has the Special Committee made that recommendation?

Dr. WINSHIP. I'm not certain for how many years that that has been made. Perhaps Dr. Errera can comment on that, or Dr. Lehmann.

Dr. ERRERA. Three, 4 years.

Mr. JONTZ. So it's been the Committee's recommendation for 4 years that a Special Inpatient Unit be established in each State, which is exactly what my legislation would do. You take the 20 centers that are now there, counting the four that are to start on July 1st—I presume those are all on line; I think your testimony reflects that——

Dr. WINSHIP. Yes, sir.

Mr. JONTZ. —and you add 30 to it, you end up with 50, which is approximately one for each State.

So why would you object to the authorization in my legislation since it is exactly what the Special Committee has recommended for 4 years?

Dr. WINSHIP. I think, Mr. Congressman, that it's not a matter of objecting to the principle that's outlined in your proposed legislation but, rather, it is that we already have that authority. We have ample statutory authority to do that if we wish. One of the problems that we would see then is that, with a requirement of that by authorizing legislation that perhaps might be mandatory for us, that we would then end up shifting funds from other places, other parts of our mental health program, unless this also carries with it appropriated funds, and at the moment it does not. That's our fear. That's a major fear.

If I may just continue, I think there is one other issue, and that is that if we focus only on one particular piece of the whole array of services that we have, we believe that we stand a reasonable chance of getting these services out of balance where we think that we want to develop and expand these services in multiple ways, across the board, and not focus a lot of energy and a lot of funds inappropriately in one particular area. But I don't believe we're arguing on whether we need to expand the program.

Mr. JONTZ. Of course, my legislation doesn't put all of the emphasis in one area. It is a continuum of care, as you currently have.

You know, as you can appreciate, this committee has authorizing responsibility and we don't have appropriating powers. If we did, life would be simpler in some ways. So it really is unreasonable to

expect this committee to be able to pass legislation which provides the funds because it's not our job.

But don't you think our situation would be better off if we could pass the authorizing legislation and then go to Mr. Traxler's subcommittee and say, you know, the Congress has set out its blueprint for how it would like to expand services to the 400,000 veterans now suffering from PTSD who aren't getting care. Do you think that would increase the prospects of us providing funds? And it is authorizing legislation, so we don't envision you taking money from somewhere else. That's why we want to pass this legislation.

Don't you think that would increase our likelihood of success with the appropriating committees?

Dr. WINSHIP. Mr. Jontz, in some other years I might be tempted to say yes to that. I believe our experience shows, though, that we're called upon increasingly over and over by authorizing legislation to do this or do that, and this would be another of those. It's not that this is not a laudable goal, because I think it is. But rather, our experience shows that that really is not what is likely to happen in these particular times. So there we would be with still another authorization and then an expectation, whether it was mandated or not, an expectation to go ahead and carry these out in this fashion, rather than to develop the growth of the entire mental health program as we can and forcing an imbalance like that.

Mr. JONTZ. Well, you keep bringing up the word "imbalance". I don't know if you think there are portions of our legislation that are imbalanced. The way I read it, you don't like any of it, so it's hard for me to figure out what you find imbalanced about our legislation.

It seems to me that one of the main reasons we have the problems we do today in the system is because, to a large extent, there was no central direction, and there was no congressional direction. I don't know if you're familiar with the history of the Marion inpatient unit. I see it isn't even on the list that we get today. It's status has been up and down. It seems to me the history of the Marion VA unit is an indicator of what the problems of the entire system have been. I guess we can disagree on the right way to remedy the situation, but it seems to me that taking money from other programs has been exactly what our approach has been from the beginning and that's why the system hasn't worked. That's what we're trying to get beyond with this legislation. But you disagree.

My time has expired, Mr. Chairman. I do have a couple more questions when my turn comes again.

Mr. ROWLAND OF GEORGIA. Mr. Rowland.

Mr. ROWLAND OF CONNECTICUT. Thank you, Mr. Chairman.

Doctor, I just have one question. One of the recurring problems of not only this issue but many issues we are facing in the veterans' areas is the coordination, the ability for the various groups, departments and agencies, subagencies, to work together. There seems to be competition for scarcer and scarcer resources. So the question I would throw out to you is, would you highlight some of the ways that you are all working together to solve these problems, the coordination, and how we're avoiding competition for the same

resources but, rather, sharing information and trying to have one total focus?

Dr. WINSHIP. I'm not sure that I'm quite on target with your question, but let me attempt to answer it, at least what I hear you asking.

In the area that we're talking about, that we've been talking about all morning—for example, about clozapine, talking now about PTSD, increasing and expanding programs there—we're talking in general about the entire mental health program of VA.

The mental health program of VA is really quite a very substantial program. It's a very large program. It has many, many components. I believe that each year we attempt, either from internal redirection of resources or, we hope, on some occasions to have funding for a specific problem and specific issues, to be able to, in a prioritized way, expand given programs so that where we believe we are on the forefront of providing institutional-based mental health care for our veterans, we can maintain that position. So that really becomes an operational issue, I think, of trying to stand back and look at the whole system and determine, particularly when funds are not coming in from a specific appropriation for a specific purpose, to look at where the best placement of funds is for that year, or that year and the next year's needed advances.

There are always a lot of crisis areas. There are always a lot of high priority areas. We have them not just in mental health but in all the areas. I think we've been reasonably successful in this whole mental health area in trying to identify those and trying to move in a very systematic way to develop, across the board, a very comprehensive mental health program.

I don't know if that answers your question or not. That's more of a philosophical statement than a specific one.

Mr. ROWLAND OF CONNECTICUT. The key word there is comprehensive health care. My concern, and I think the concern of many of my colleagues, is that we have internal competition and lack of coordination. So I guess the point I wanted to drive home is that do you feel there is the coordination of resources, that there is interaction to the degree that we are delivering comprehensive mental health care to the veteran, and that we're not duplicating or moving in different directions? If you feel confident in that, then why do you would be my question.

Dr. WINSHIP. Yes, I feel reasonably confident in that because, for all of these programs, we have a single program which really has oversight of all of those. Dr. Errera is in charge of that program and I would like to ask him to make some comments about that.

Dr. ERRERA. I think one of the unique aspects and one of the major strengths of VA is that we have an integrated system. There are very few national systems that have both outpatients and inpatients. And our integration goes beyond that. We have outreach, we have Vet Centers. This gives us the comprehensiveness you were talking about.

Mr. Jontz, I would disagree that we are a failure. I think, in an area of the treatment of PTSD, where we are just beginning to learn, we are really the leaders. We are not the leaders in Marion, and I'm sorry about that. That's true. But we have devised, Dr. Blank and I, the Special Committee, the National Center, a

number of treatment modalities, and they're integrated. We are developing them. That's the continuum of care that I think we're talking about and that we are evaluating, so that we will know what works better. And should there be more Vet Centers, should there be more outpatient PCTs; should there be more inpatient units.

I don't think we know those answers yet and, incrementally, we're studying them. We have added—as Dr. Winship mentioned, we have been adding every year to this continuum.

Mr. ROWLAND OF CONNECTICUT. Thank you.

Mr. ROWLAND OF GEORGIA. Thank you.

I have some questions I want to submit for the record. I won't ask them because of time constraints, but I will come back to Mr. Jontz, if he has some questions.

Mr. JONTZ. Thank you, Mr. Chairman. I do want to try to clear up one particular item in your testimony, Dr. Winship, that perhaps we can't clear up this morning.

My legislation does not contemplate the creation of a new advisory committee. It contemplates providing statutory authority for the existing Advisory Committee on the Readjustment of Vietnam Veterans, which we have changed in title to delete the word "Vietnam", and we have changed the composition somewhat.

But my understanding is that this committee is not authorized, that it has had some problems such as failure of the committee to meet in May because of a lack of available dollars. Our intention with this provision is simply to put authorization into law for the existing committee, which hopefully then would help to lead to the modest funding that would be necessary for it to continue to operate as it has.

Would you be opposed to that?

Dr. WINSHIP. We're certainly not opposed to having that committee. In fact, we do continue to have the committee. And let me just speak to our general opposition to the legislation once more.

I think it is not, Mr. Jontz, that we object to any of the principles which are being outlined in that legislation. It is that we believe we already have the authority. I think as far as the committee is concerned, sure, there was a time when there was a glitch that caused difficulty in meeting, but it's been going on over several years now and that really has not been a major problem.

It has been a very productive committee. We don't see the need for the legislation to do the things that it calls for because we already have that authority.

Mr. JONTZ. Well, the question is really whether you have legal authority. Clearly, you have legal authority to establish additional inpatient units. Clearly, you have legal authority to establish additional bed space. I don't know about the pilot program for the halfway house. It might interest you to know that this was a recommendation made to me by a medical center director, who thought the continuum of care was not as broad as it should be. The recommendation I received was, why not try this out, like we do for drugs and alcohol, and see if it works. It might work for PTSD, too, to provide some more complete continuum of care on a pilot basis.

I don't know whether you have statutory authority to do that or not. But there really isn't disagreement about your statutory au-

thority. The real disagreement is, I think, with regard to the pace at which you are moving.

Your own committee has recommended one inpatient unit for each State for 4 years. I guess the list of inpatient units has increased a little bit. But I wish your office took the calls that our office did from the veterans who have concerns about the program in Marion, IN, which has not been centrally funded. I don't know about these veterans that are waiting in line all across the country, combat veterans, to get into these programs. I appreciate the fact that you're moving forward, and I appreciate the fact that in many ways you have been leaders. But is the VA proud of the fact that in 1988 only 10 percent of those 480,000 veterans that are suffering from full-blown PTSD received care? Surely you're proud of the treatment that those 10 percent are receiving, but I find it hard to understand why you would resist this encouragement from the Congress to take some programs that have proven their value, put them on a sounder statutory basis, and avoid some of the problems that Marion, IN exemplifies for lack of any central funding, lack of any central authority to even establish the program.

So I guess we disagree about the means to get to the same place, and I offered this legislation not because I think you have the authority to do many of those things, but because the pace seems very slow to many of those veterans and to many Members of Congress, who feel that we have an obligation to them to be fulfilling more quickly than what we are now.

Dr. WINSHIP. Let me just make one more comment about that pace, and then maybe Dr. Errera, who is sort of fidgeting there, would like to say something, too.

The pace is probably not only because of funding issues, or not only because of authority problems, authorization problems. Part of the pace is because we're feeling our way all the time on what's good and what we need to be doing. We need to continue that because we are, I believe, that we can claim rightfully that we are, in fact, in the forefront of the world on how to manage this kind of problem. Therefore, it is our judgment and our decision and, therefore, practice, to do that pretty carefully and not go running into one particular area, putting all our resources there, where we really need to develop a number of different programs.

I would like to ask Dr. Errera to comment on that.

Dr. ERRERA. You said what I was fidgeting about, in terms of the pace of medical progress. I think that is what you're addressing and what's frustrating.

Let me also remind you that the recommendations of the PTSD Special Advisory Committee were also for outpatient PCTs, not just inpatients.

Mr. JONTZ. And I support that. But for how many years have they made that recommendation?

Dr. ERRERA. They have been making the recommendation and we have been developing it. For us to implement, across the board, a number of new treatment modalities that are not yet fully evaluated would not be wise. I think we have an obligation in the medical profession to evaluate the treatment modalities that we introduce; one of our problems is that we don't do enough of that.

Mr. JONTZ. Well, you know, your testimony speaks glowingly of the 16 inpatient units and how you are establishing four more this year, so apparently you have some experience with the modality. Actually, I think you've had 12 years of experience from the first inpatient unit.

Dr. ERRERA. The evaluation, Congressman, started 6 months ago.

Mr. JONTZ. How many years did you have these facilities operating without an evaluation?

Dr. ERRERA. How many years have we been doing open heart surgery, sir, without any evaluation? How many years have we been doing tonsillectomies without evaluation?

Mr. JONTZ. Well, I don't know.

Dr. ERRERA. I think it's terrific that VA is introducing evaluation at this time for these treatment options.

Mr. JONTZ. I am pleased that you are, also, and I'm sure there are many veterans out there who are just pleased as punch that they're going to wait on any care while you're evaluating.

Dr. ERRERA. But they're not waiting and unattended. They are——

Mr. ROWLAND OF GEORGIA. I think that probably we could beat this dog for a long time, and maybe we ought to stop here, since we do have a couple more panels.

Mr. JONTZ. I appreciate the patience of the Chairman.

Mr. ROWLAND OF GEORGIA. I appreciate the situation that the gentleman addresses here.

Dr. WINSHIP. We'll be glad to answer any other questions that you want to submit.

Mr. ROWLAND OF GEORGIA. Thank you very much. I appreciate your appearance here this morning.

The next panel is Mr. Fred Gusman from the DVA Medical Center in Palo Alto, CA; Dr. Dennis Charney, from the DVA Medical Center in West Haven, CT; Dr. Spencer Falcon, Chairman of the Chief Medical Director's Special Committee on PTSD; and David P. Niles, from the American Association of Counseling and Development.

Thank you very much, gentlemen, for being here this morning. We will start with Mr. Gusman.

STATEMENT OF FRED D. GUSMAN, DIRECTOR, CLINICAL LABORATORY AND EDUCATION DIVISION, NATIONAL CENTER FOR PTSD

Mr. GUSMAN. Thank you, Mr. Chairman. It is a pleasure to be invited. It was the House of Representatives—in fact, I believe probably in this room—that gave me the job of being part of the Chief Medical Director's Committee on PTSD, besides being director of the first inpatient program in the country and now the director of a division of the National Center for PTSD.

I would like to say that there's been a tremendous amount of progress since I last was here, but we still have a lot of work to do. We still have many issues that have not been dealt with that are very complicated, and myself as a clinician find them somewhat overwhelming. Those areas that we speak to are the issues of access to care and what types of care.

Right now, I think we have learned a tremendous amount about post-traumatic stress disorder, but I would agree with Dr. Errera's comment, we still are in the learning process. As we move down the road, what we have learned is that this disorder is very complicated. We are no longer treating just the veteran who requires to sit in a group and talk about his war-related stress but, rather, a veteran who has multiple problems, anything from family issues—We have the veterans who were admitted into the service who have learning disabilities, and who require special types of treatment so that they can understand how to deal with their problems. We have veterans with tremendous medical problems and those veterans who have comorbidities, such as PTSD and alcohol and PTSD and substance abuse, et cetera, et cetera.

Mental health and Behavioral Sciences and the Chief Medical Director's Committee on PTSD, with the support of Congress, has been able to establish services for PCT teams, inpatient programs, new substance abuse programs, and all these are very laudible and well needed services. But we are still faced with the issue of geographical distance, waiting lists, et cetera. It is my hope and my belief that, with the support of Central Office and the support of Congress, these issues will be resolved in the immediate future.

I also believe that the National Center for PTSD, which was also part of the legislation from this committee, will also play an instrumental part in establishing these adequate and needed services.

Thank you.

[The prepared statement of Fred D. Gusman appears at p. 138.]

Mr. ROWLAND OF GEORGIA. Thank you very much.

Dr. Charney.

STATEMENT OF DENNIS CHARNEY, M.D., DIRECTOR OF CLINICAL NEUROSCIENCE, NATIONAL CENTER FOR POST TRAUMATIC STRESS DISORDER, DVA MEDICAL CENTER, WEST HAVEN, CT.

Dr. CHARNEY. Thank you, Mr. Chairman, members of the subcommittee. I don't have a prepared statement, but in my role as Director of the Neuroscience Division of the National Center for PTSD, I would be pleased to answer questions regarding recent research findings in PTSD.

Another position I have is codirector of one of three VA-sponsored schizophrenia biological research centers, in which we focus on aspects of clozapine's treatment and mechanism, so I would be happy to discuss issues surrounding clozapine.

Mr. ROWLAND OF GEORGIA. Dr. Falcon.

STATEMENT OF SPENCER P. FALCON, M.D., CHIEF OF PSYCHIATRY SERVICE, VA MEDICAL CENTER, ANN ARBOR, MI, AND CHAIRMAN, CHIEF MEDICAL DIRECTORS SPECIAL COMMITTEE ON PTSD

Dr. FALCON. Thank you, Mr. Chairman.

I am pleased to appear here today to discuss these two matters of the availability of general mental health treatment with specific reference to post-traumatic stress disorder, and the potential impact of the prescription of clozapine upon the Department of Veterans Affairs.

In many ways, it is appropriate that these two issues be discussed together, in that both PTSD special programs and the possibility of funding clozapine therapy can been seen as potential enhancements or additions to the basic core mental health funding that is available through the Department.

A concern with this type of new or dedicated activity is that it is at times a redirection of old funding and, therefore, could have an adverse impact on other parts of the total mental health care available.

First, in regard to PTSD, the Special Committee, as you all know, has been in existence since 1984. Over that time, we have taken the opportunity to make a lot of recommendations and comment on the ability of the Department to provide diagnostic and treatment services to veterans with PTSD. Substantial progress has been made in the availability of high quality PTSD treatment within the Department over the past decade. This has resulted in the development of a continuum of care needed by veterans, which includes the outreach operations of the Vet Centers, the outpatient PTSD Clinical Teams, the Specialized Inpatient PTSD Units, and now, the most recent addition, the substance abuse/PTSD units.

Much of this program development preceded the release of the 1988 NVVRS report that gave us the staggering numbers of veterans with the disorder, and the very low market penetration VA: the 10 percent of the 480,000 who are actually being treated.

Currently, I think it is important to keep in mind that all the PTSD treatment enhancements that have been made have been made to a part of the psychiatric programming that is the general psychiatric programming; that even with the enhancements for the treatment of PTSD, and special funding for substance abuse, much of the core mental health programs are deteriorating, and continuing to deteriorate. Much of this is the result of the RAM incentives for decreasing the length of stay and increasing the number of episodes of care. Much of it is the result of the continuing difficulty in recruiting psychiatrists.

For example, in the new PCTs that were funded by last year's legislation, 34 percent of the psychiatry positions were still vacant as of March of this year. This stacks up with 20 percent for psychiatry in general. These vacancies certainly hurt the availability of care.

The Special Committee continues to recommend that, in order to meet the VA's priorities, we provide adequate access to all of our special inpatient programs; and that it is important that we adequately support these regional and national centers where a veteran with PTSD may receive treatment where other treatments have failed. In many ways, the struggle that we have seen with the Specialized Inpatient PTSD Units is very similar to what is seen in the other large psychiatric bed sections, where the number of staff per patient on the ward is low, and the availability of care has deteriorated.

Now, if I could, I would like to comment briefly on what we heard all morning on clozapine. I would like to comment as a Chief of Psychiatry from the field. I would like to express my concern over the exclusion of clozapine from the standard VA psychiatric

mental health delivery system because of the way the monitoring package is set up.

At the Ann Arbor VA, as in other places around the country, about 30 percent of our inpatient and outpatient workload will be schizophrenic patients. These schizophrenic patients are frequently very complex patients. As we look at the issue of using an external vendor as a patient monitor, I feel that this could substantially compromise the quality of our patient care.

One of the characteristics of our patients is that they don't have a single diagnosis. It is not uncommon to be providing treatment for a veteran patient with a primary psychiatric illness, such as schizophrenia, who also has cardiac disease, hypertension, diabetes, and four or five other things. In many of our aging veterans, this means a combination of multiple medications. So, if you take out one drug, one case management system, I believe the Sandoz-required CPMS system fragments care and provides the possibility for very significant problems in the direct care delivery.

I would be reticent to have this drug provided on my service under the control of an external case manager. We still have many men in our outpatient programs and in our long-term psych units who had their first psychotic episodes when they were 18 and enlisted for World War II and the Korean war. Their care up to now has been delivered entirely by the Department. I would be loathe to transfer the oversight of their care to a proprietary case management company. The cost is prohibitive, and it surely will distract from the availability of care for other veterans and from our historical commitment to their total patient care.

I believe that this will be the case within the psychiatry services. Our funding now is marginal. With the addition of clozapine and this bundle package, it will become truly impossible to deliver this needed product.

Thank you.

[The prepared statement of Dr. Spencer Falcon appears at p. 144.]

Mr. ROWLAND OF GEORGIA. Thank you.

Dr. Niles.

STATEMENT OF DAVID P. NILES, ON BEHALF OF THE AMERICAN ASSOCIATION FOR COUNSELING AND DEVELOPMENT, AND THE AMERICAN MENTAL HEALTH COUNSELORS ASSOCIATION

Dr. NILES. Good morning, Mr. Chairman. My name is Dr. Niles. I am a clinical mental health counselor. I am the chairman of the Post Traumatic Stress Disorder Committee for the American Mental Health Counselors Association, which is a division of the American Association for Counseling and Development. I also serve as the deputy chair for PTSD and Substance Abuse Committee of the Vietnam Veterans of America. I am a Vietnam veteran who served two tours of duty in Vietnam as an infantry platoon leader and as an infantry company commander. I am a retired infantry Army Lieutenant Colonel.

I did not know that Sandoz was here this morning. I will also tell you that I'm a certified medical psychotherapist with the American Board for Medical Psychotherapists. I spent 4 years at the Psychi-

atric Institute of Washington, D.C. The last 2 years I was associated with clinical neuroscience program there gathering data for Sandoz and clozapine, the over-the-county drug name for Clozaril. I will be glad to share my concerns with this in treating PTSD if asked by the committee, and I do have some. But today I'm talking to you as a clinical mental health counselor representing AACD, which has 56,000 members, 12,000 members in the mental health counselor field.

As the bill accurately points out, there are 800,000 vets suffering from PTSD. Approximately a third served in Vietnam. It is time to ask why only 10 percent have come in.

I want to get out of the clinical picture and spectrum that we're hearing from today. Clozapine would be another neuroleptic straightjacket in the eyes of Vietnam veterans. I want to focus on PTSD, the clinical diagnosis of PTSD from a mental health perspective, and access to service, and recruitment of qualified PTSD professionals and paraprofessionals.

Fundamentally, Vietnam veterans, along with all victims of trauma, do not want to be diagnosed as mentally ill or suffering from a personality disorder. This is labeling. In other words, to come in to get the help from VA, you have to be labeled as crazy or diagnosed under Access II of the DSM-III-R. PTSD, in reality, serves a normal reaction by human beings to abnormal life experiences and/or events. PTSD is not a mental illness or personality disorder from this perspective. This concept receives dramatic support from the Twin Study of 715 twins, one of which served in Vietnam and one that did not. There is a ninefold increase in the prevalence of PTSD comparing these twins, one who experienced a high level of combat in Vietnam and the other who did not serve in Southeast Asia. The key implication of this study is that PTSD is related to traumatic stressful life experiences and is not a result of characterlogical or personality disorders or bad parenting. PTSD is the result of the traumatic violence experienced in combat while in Vietnam, or exposed to other natural disasters such as earthquakes or man-made disasters like rape, incest and molestation.

The fact that PTSD is not a mental illness or personality disorder is further demonstrated by a study I conducted of 244 active duty colonels and lieutenant colonels on the Department of the Army staff in the Pentagon. This study was conducted under the auspices of the George Washington University where I also serve as an adjunct professor. My study finds an 18 percent alcohol abuse rate and a 20 percent PTSD rate among these active duty officers. Upon further analysis of the actual data, I can argue for a 30 to 33 percent alcohol abuse rate and PTSD rate. This equates to one-third of the sample and is closely associated with the findings of other studies, that a third of the vets are suffering from PTSD and substance abuse.

These findings, sir, should not be surprising to anyone. The basic question is why should the veterans on active duty and in our reserve forces be any different from those veterans who are no longer actively serving our national defense. The key implication is that these active duty veterans avoid seeking help because of the stigma associated with PTSD; specifically, that it's a mental illness or a personality disorder. I can assure you, sir, as a retired infantry

Army lieutenant colonel, and a practicing clinical mental health counselor, that many of my colleagues, in fact, are having problems associated with PTSD and alcohol abuse.

On my instruments that I sent over to the Pentagon I received comments like, "Thank God, somebody is finally doing something for us." You can find this if you talk to the spouses and the children. But the responses were sent back to me because there was no way of identifying these people. When I came out with my findings, the Army Times was going to do a study, or release the story on my 18 percent alcohol abuse rate. When DOD was contacted, they started to stonewall it and said no, we're only finding a 9 percent rate. The week before my story broke, the Army admitted that in their 10-year study, they leave out a bunch of heavy drinkers and, if added, it was 16.7 percent. My 18 percent took $200 out of my own pocket and took 30 days. There's institutional denial.

The key point, sir, that I'm trying to bring out here is that there are a large number of veterans who are fully functioning and suffering from PTSD that want to come in for help but do not want to be diagnosed as crazy or screwed up. There is a large group of people out there fully trained to help these veterans. That is the mental health community.

The reason that some of the medical experts here are having trouble answering your questions of Clozaril and PTSD is that this is a neuroleptic used in Access I diagnosis, and the medical community is desperately trying to keep PTSD in the DSM-III-R under a personality disorder, which is Access II. In 1952, it was called "war neurosis". In 1968, the psychiatric community through it out of DSM-II because they referred to it as a "compensation neurosis", accusing the Korean veterans of wanting to act crazy to keep on getting compensation. Right when the psychiatric community was throwing it out of the DSM-III-R, we vets were in Vietnam fighting the Tet offensives. It wasn't back into the DSM-III until 1980, in which one of the criteria was called "survivor guilt". Then, in 1987, for unknown reasons, survivor guilt was thrown out as one of the criteria, and anybody working with anybody suffering with PTSD knows that survivor guilt is a key criterion that you have to work in a therapeutic relationship.

I'm running out of time, but my thrust here, sir, is that I'm networking with the Vietnam Veterans of America. We already have proposals in place that we're trying to develop that I think will help you save costs. The real experts in this field are the Vietnam veterans. My dream, along with Vietnam Veterans of America, is to get out there and train the Vietnam veterans as paraprofessionals. We can start working with them and networking with the American mental health councils that I have in my network, go out and put the workshops on, train what the symptoms are, cut through the nonsense, look at your studies, get them off the alcohol and everything else, and their close association between the veterans and the professionals will start helping the family, the spouses, the kids. That's kind of the trust of my testimony. It's in the written aspects of my portion.

I thank you for the time.

[The prepared statement of Dr. David Niles appears at p. 157.]

Mr. ROWLAND OF GEORGIA. I agree with you, that there is some sort of stigma attached to being mentally ill. We even do it when we pass legislation relative to insurance. We put some kind of restrictions on it. Mental illness is just as incapacitating as physical illness is. I think you make a good point, that there are a lot of folks out there that would come in for treatment, except they feel they would be stigmatized when that happens. So I think that's an excellent point that you make.

I do have several questions I want to submit for the record. I will do that in the interest of time here. Let me recognize Mr. Jontz at this point.

Mr. JONTZ. Thank you, Mr. Chairman. I will try not to be lengthy. These were excellent statements.

Dr. Falcon, I think we have covered pretty well the recommendations of the Special Committee for inpatient facilities. Obviously, the committee wouldn't recommend expansion if it didn't feel like they were an effective model to use in implementing that recommendation. You have also recommended the clinical teams, which I would certainly be supportive of, although we didn't address it in the legislation.

Let me ask you about the Vet Centers. Your committee has not made specific recommendations with regard to expanding Vet Centers, but tell me this. You know the results of the RTI study with regard to the high incidence of PTSD in Hispanics, in black veterans, in minority veterans overall. Would you care to comment about the role that the Vet Centers play in terms of addressing the needs in that underserved population where the incidence of PTSD is so high?

Dr. FALCON. I think that that has been one of the real successes of the Vet Center system, both in the hiring of minority individuals as counselors; and in access, with the placement of these storefront operations in different parts of the cities for accessing these populations. I think the work they have done has been very important for the past decade in that.

I also feel that they continue to really serve that role both pre- and post-hospitalization, and in concert with the rest of it. I think they have done a much better job in that area than the medical center outpatient clinics in that particular regard.

Mr. JONTZ. So the 27 percent incidence of PTSD in Hispanic veterans and the 20 percent, approximately, incidence in black veterans, compared to the 13 percent incidence in white veterans, is a real problem in terms of the gap in services that are now there, and what you're telling the committee is that the Vet Centers have been effective in that regard. Yet, we have cities as large as Toledo, OH, and Nashville, TN. Those are cities with substantial minority populations that have no Vet Centers.

Do you think, if we looked at the map nationwide and looked at the numbers of particularly minority veterans, where we would expect the incidence of PTSD to be high, that we could find several communities that had significant populations where a Vet Center might be constructively located? Do you think that's reasonable?

Dr. FALCON. Yes, I think that's reasonable. I certainly couldn't say that it's not reasonable. I think the central thing here is the issue of whether or not we can demonstrate this reasonable point,

in terms of the access to care, whether there are real barriers to care based upon the absence of Vet Centers in cities like this.

One of the things that the Special Committee is currently working on is trying to compare the findings from the National Vietnam Veterans Readjustment Study with utilization work, surveys and some other things that we're doing this year, to try to find out where the care is being delivered and where it's not being delivered.

Just to specifically answer your question——

Mr. JONTZ. So, in fact, were the Congress to give some direction to the VA to establish some additional Vet Centers, the information that your committee is developing would be available to help them do that in a rational way, so that we're using resources to meet the needs that did exist?

Dr. FALCON. That's right. The purpose of the study is to find out where there is a need for all types of care, not just Vet Centers——

Mr. JONTZ. Sure. So, in fact, it would also be helpful in terms of locating inpatient facilities?

Dr. FALCON. That's correct, Congressman Jontz.

Mr. GUSMAN. I would like to comment on that for just a second.

Mr. JONTZ. Yes, sir.

Mr. GUSMAN. I'm sure you're familiar with Public Law 101-144, initiated this year, which basically designates through the National Center for PTSD to try to determine what that problem is and reaching out to special populations, women, blacks, Hispanics, Pacific Islanders, Asian-Americans, et cetera.

I will probably say something that will sound strange coming from me, because I've been a primary advocate and I've been the person who has pointed out many of the problems in delivering services to this particular population. But I think, as this disorder becomes clearer, that it's more complex, it's not something that one can just quickly deal with by, as I said earlier, by just talking about war issues, that the same thing goes for minorities. There are reasons why minorities don't access health care systems aside from the VA. Those issues need to be looked at as we try to provide services, as opposed to just putting in special inpatient units or any kind of services out there. I think we have to really look at how we do that. I think we have to do it. I'm not saying wait forever. What I'm saying is, in tandem, we need to make sure that what we're doing is not just a duplication of services but are addressing the real issues.

I'm not so sure we know why minorities—and I'm one of those—do not go to the VA en masse. I'm not so sure anybody can really address that, other than the sort of general comment, which is there are cultural issues and differences. If that's true, then we have a bigger problem.

Mr. JONTZ. I agree completely, but the prospect of getting minorities into the VA when you have a Vet Center in Gary, IN, even though you have the Adam Benjamin outpatient clinic down the road ten miles at Merrilville, that helps significantly—and I think the same would be true of Toledo, which, by the way, is larger than Gary.

Mr. GUSMAN. Right. I would support services. All I'm suggesting to you, sir, is that we now I think are learning a lot about this. This is becoming more clearly a science.

With all due respect to the Vietnam veteran, or any war veteran, it is a very complicated problem now and we need to not just think about establishing one item—be it an inpatient unit or whatever. That's all I'm saying. I would want the committee be able to recognize that this is very complex.

Mr. JONTZ. Thank you. I find your testimony very helpful in terms of outlining what is happening, and your comments about areas of concern I think will be helpful to the committee.

I have no more questions, Mr. Chairman.

Mr. ROWLAND OF GEORGIA. Thank you, Mr. Jontz.

Mr. Rowland.

Mr. ROWLAND OF CONNECTICUT. Thank you, Mr. Chairman. I would like to thank the gentlemen for testifying today. I would like to ask a question or two of Dr. Charney.

Doctor, you have recently completed some research which suggests that the symptoms of PTSD may have a biological basis. What impact might this research have on the VA's current methods of treating veterans with PTSD?

Dr. CHARNEY. First perhaps I can review what we're finding and then briefly mention some of the possible implications.

What we think we're finding—and it's still ongoing research—is that, despite the trauma being 20 years ago in many cases, that there is abnormal central nervous system and peripheral neurophysiological changes that we can identify in the veterans.

For example, under many situations they have abnormally high heart rate and blood pressure responses. The amount of adrenaline, or what we call catecholamines, is elevated in their blood and other body fluids. We have now tests that can identify that their brain adrenaline or catecholamine system is abnormally hyperreactive, so when they're stressed, even stress unrelated to their combat stress, but other forms of stress, it abnormally activates their brain adrenaline systems which results in symptoms that can produce disabilities and family and social difficulties.

In fact, when you look at this data in total at the present time, it may represent among the first evidence of an environmentally-induced stress causing what we would call brain chemical dysfunctions that can last a long period of time.

This could have implications for other forms of traumatic stress, like that mentioned before, such as catastrophic earthquakes, incest, rape, et cetera. Brain and chemical changes may result from these forms of stress also.

Now, as to what implications may that have, one implication which is relevant to some of the prior testimony is that it gives us a different perspective toward understanding the nature of PTSD, that it is a response to a horrible situation that is out of one's control. It's uncontrollable stress. It is not due, in the vast majority of instances, to any kind of personality weakness or abnormality or family problems, et cetera. It is, in a sense, a normal response to a terrible situation that now is lasting for a long period of time, remains out of one's control, that then can lead to secondary problems which we now see as part of the PTSD syndrome, such as

family problems, not being able to work, and substance abuse issues. In this context, the research has helped us better conceptualize the PTSD problem.

Now that we can do that, we can go on and develop better treatments that may involve different forms of psychotherapy, vocational training, and perhaps trying to develop medications that, at least on a short term, may be able ameliorate the symptoms associated with PDSD.to reverse what we're identifying.

Mr. ROWLAND OF CONNECTICUT. At the medical center in West Haven you have also had some experience with the Clozaril issue. Would you comment on that experience?

Dr. CHARNEY. I think our experience is similar to those throughout the rest of the VA system. It is a tragic situation in which we have veterans with schizophrenia, who are treatment-resistant, and we have a drug that we know will help at least 40 to 50 percent of them, and we can't use it. In my medical center, we have approximately a hundred or so veterans with schizophrenia that is treatment-resistant. We currently have five patients on clozapine, and we have no mechanism at this point in which to provide any additional patients with clozapine. The patients know it's an available drug, but we can't get it to them because it is just so expensive and the funds are not available.

A second point that I would like to make, which has not yet been made in the hearing, is the issue around research, which is a very important one. Clozapine does represent a breakthrough. It is a novel antipsychotic drug. It is better than the other antipsychotic drugs. We don't know why, though. We don't know what aspects of clozapine make it better than other drugs.

Because of the limitation of funds, we cannot conduct research into discovering what makes clozapine unique VA order to then make a better "clozapine" that does not produce agranulocytosis. When we submit grants to the VA and the National Institute of Mental Health, we can't include the cost of $9,000 per patient just to provide the drug. Sandoz has agreed, in principle, to support some of these studies, but it is not nearly going to meet the demands by the large number of studies designed to determine how clozapine works.

One last point, and that is, the VA has organized a cooperative study to look at clozapine on a large scale. We are proposing at this point to study approximately 450 VA patients with treatment-resistant schizophrenia to look at the full clinical impact of clozapine. Most of the studies that have been done are short term, only 8-week studies. We propose a 2-year study that has received preliminary approval. We have gone through the first step of getting approval through the VA Cooperative Studies Program. But the question they have now given us is how are you going to pay for it. We don't have the money, which will come to $8.1 million, to support this kind of study, if we have to pay $9,000 per patient.

Mr. ROWLAND OF CONNECTICUT. Thank you very much, Doctor.

Mr. Chairman, I have some additional questions I would like to submit for the record.

Mr. ROWLAND OF GEORGIA. I appreciate that, and I do have some questions to submit for the record. But I just want to ask one ques-

tion here that I asked earlier, if you've had enough experience with clozapine to answer this question.

Are the side effects of clozapine more life threatening than phenothiazines and other psychotropic drugs that are now used without this type of monitoring system?

Dr. CHARNEY Is that addressed to me, sir? Maybe I can take a crack at it.

Yes, I do think the side effects are more life threatening, especially the agranulocytosis.

Mr. ROWLAND OF GEORGIA. Well, I'm asking about all side effects.

Dr. CHARNEY. In general, I think that clozapine has more side effects than other neuroleptics, except for its low incidence of tardive-dyskinesia and extrapyramidal side effects. The seizure propensity is substantially higher than other neuroleptics; it produces more cardiovascular changes than other neuroleptics. Therefore, use of clozapine requires a comprehensive medical management. That's why I'm against taking it out of the doctor's hands, because it's not just the agranulocytosis but it's the other side effects that you also have to be aware of to provide adequate care.

Just one other comment in relation to clozapine that was alluded to by you before, and that is, is it analogous to chemotherapeutic drugs. We don't have these monitoring systems for chemotherapeutic drugs used for cancer. I submit that schizophrenia, if not as bad, is worse than having cancer. It is a chronic disease and it is, in many cases, totally disabling. It is particularly disabling for patients who need clozapine. These patients have high suicide rates, and I think we have to view the need for clozapine as great as the need for chemotherapeutic agents in patients with cancer.

Mr. ROWLAND OF GEORGIA. Thank you.

Dr. Falcon.

Dr. FALCON. I would like to answer from the standpoint of a tangent, that when we use the drug Coumadin, or warfarin, as an anticoagulant, we will do a weekly prothrombin time, sometimes for years, frequently for years, on a person that has a need to be chronically anticoagulated. As physicians, we have seen this in—you know, it's business. I mean, this is what we do. This is our job. We have never felt the need to contract out somebody doing our weekly pro times. So I think, conceptually, we've gotten a little mixed up with this issue because one of the tenets of being a physician is that you treat patients; you don't treat diseases. Clozapine and the clozapine management system treats a disease. This disease is in a patient who's a human being, who's a veteran. The rest of his care is under the responsibility of the VA hospital and the primary physicians there. I think we can't lose sight of that very critical fact in here.

The thing we are always accused of, as modern American physicians, is that we treat diseases, we split a patient up into 50 different specialties and treat them piecemeal. This is one of the most piecemeal ways of doing it, to split it up, even more than specialities, to take out one drug and one particular side effect.

We do a thousand CBCs, white blood counts, per month at the Ann Arbor VA. The VA probably does two million of these a year. We have the technology to do this test. This is not a very complicated system. This is a controlled——

Mr. ROWLAND OF GEORGIA. You can do a differential, too, can't you?

Dr. FALCON. That's right. And this is a controlled system. I don't think there's any question that we have the capability.

I agree with Dr. Charney, that if these people are treated on my service, just as they're treated on his service, I have very severe concerns about the rest of their complicated care for seizure disorders, the cardiac side effects.

Mr. ROWLAND OF GEORGIA. Dr. Niles.

Dr. NILES. I would like to make just two points—and I'm being a real devil's advocate. I'm a vet right now in responding to this.

To those patients who respond to clozapine, it's absolutely beautiful to see. My concern is that it is a neuroleptic that can kill if you don't catch it. The reason vets have not come into the VA is that basically they don't trust the VA. Can you imagine the rippling effect if one vet dies? I can hear the vets out there right now. "See, the VA, now they're even using drugs to kill us." I'm saying that you need to proceed with this very carefully.

I would also like to make another point as a mental health counselor. I am very happy to see the committee very concerned about the agranulocytosis that can cause death. I would put on the other shoe, though. I hope the committee is beginning to be as equally concerned of the 55,000 vets who have committed suicide—and the rate is climbing. We don't have time for more research on clozapine and neuroleptics and all this other stuff. We need to get programs out there right now, dealing in therapy, to bring the vets in and start helping them understand what the violence did to them when they were 18, 19 and 20 years old and get on with it. So I'm very concerned about the agranulocytosis, but I'm equally concerned about the vets that are blowing their brains out. I think we have to get moving.

Mr. ROWLAND OF GEORGIA. Thank you very much, gentlemen. I appreciate your being here today, and we appreciate your patience.

The last panel is Mr. Robert Manhan from the VFW; Mr. Samuel Walsh and Mr. Frank Buxton of The American Legion; Mr. John Bollinger from the PVA; Mr. David Gorman of the DAV; and Mr. Paul Egan from the Vietnam Veterans of America. Gentlemen, thank you all very much for being here this morning. Let's start with Mr. Manhan, and let's see if we can keep our testimony within 5 minutes.

STATEMENT OF ROBERT D. MANHAN, SPECIAL ASSISTANT, NATIONAL LEGISLATIVE SERVICE, VETERANS OF FOREIGN WARS OF THE UNITED STATES

Mr. MANHAN. Thank you very much, Mr. Chairman. It is my pleasure to represent the 2,800,000 members of the Veterans of Foreign Wars. That figure does include our Ladies Auxiliary.

Briefly stated, the VFW strongly supports H.R. 3037. We note that it does support a VFW resolution that was passed by our national organization last August. A copy of our resolution is attached to the statement. The long title is "Expand PTSD Treatment Program".

Generally, we like the bill for three reasons. First of all, by looking at its formal title, we notice that it incorporates PTSD treatment for veterans of all conflicts in addition to just targeting on the Vietnam-era veteran.

Secondly, we believe the overall thrust of the bill will provide for a greater continuum of care for veterans who suffer from PTSD, and we know that one of the signatures of PTSD is that it is a chronic and recurring disability.

Lastly, the six parts of the bill generally build on the existing array of VA PTSD treatment facilities and/or services. So, collectively, we think it's a good effort moving in the right direction.

Thank you, Mr. Chairman, and members of the committee.

[The prepared statement of Robert D. Manhan, w/attachment, appears at p. 161.]

Mr. ROWLAND OF GEORGIA. Thank you, Mr. Manhan.

Mr. Walsh.

Mr. WALSH. Thank you, Mr. Chairman. With me this morning is Mr. Buxton, who will present out summary statement.

STATEMENT OF FRANK C. BUXTON, DEPUTY DIRECTOR, NATIONAL VETERANS AFFAIRS AND REHABILITATION COMMISSION, THE AMERICAN LEGION

Mr. BUXTON. Good afternoon, Mr. Chairman, and members of the subcommittee.

The American Legion appreciates the opportunity to express its views on the provision of mental health care services to veterans suffering from PTSD and to comment on H.R. 3037.

The subject of post-traumatic stress disorder and the manner in which the VA approaches the issue is of great significance to The American Legion. The American Legion believes that additional veteran outreach centers are needed and that the staffing at some of the existing centers should be augmented. Based on the findings of a demographic analysis and a needs assessment, The American Legion supports a modest expansion of the veterans outreach program.

In addition, we encourage the expansion of veterans outreach services to veterans of World War II, the Korean conflict, and those veterans who served in hostile action after May 7, 1975.

Mr. Chairman, with respect to the second provision, section 3, there are 16 inpatient PTSD units, SIPUs, at VA medical centers around the U.S. that treat veterans with critical cases of PTSD. An additional four inpatient units are planned to be activated by the end of fiscal year 1990. The American Legion is mandated to urge Congress and the administration to provide adequate funding for the continued operation of the PTSD inpatient treatment program and for its badly needed expansion.

As with the Vet Centers, we believe a thorough demographic analysis and a needs assessment must be accomplished to determine the number, size and location of the proposed new PTSD inpatient treatment programs. We are also mindful that new resources would be required to accomplish this expansion.

Mr. Chairman, section 4 requires the Secretary to allocate $10 million of the amount available in fiscal 1990 for the provision of

contract treatment services for PTSD. According to available information, the Readjustment Counseling Service has been appropriated $5 million for fiscal year 1990 for provision of these services. We would have to find a new funding source, Mr. Chairman, in order to increase those amounts.

The American Legion would support increasing the funding available for PTSD contract care but cannot support reduced funding available for outreach centers to accomplish that goal. We feel it is more cost effective to provide PTSD counseling and related services to veterans in outreach centers and VA inpatient treatment facilities, and by modestly expanding these programs, then less funding would be required for contract care.

~~Section 6 of the~~ measure would mandate the establishment of an advisory committee on readjustment of veterans. Mr. Chairman, The American Legion, in general, supports the intent of this measure. However, we must point out that this proposal would significantly alter the nature of the Secretary's administratively established Advisory Committee on the Readjustment of Vietnam Veterans, which is mainly consumer oriented. This proposal, we believe, provides too many Federal employees as ex officio members of the committee. Since the Secretary's advisory committee is focused on the readjustment of combat veterans, The American Legion strongly believes that the proposal to statutorily establish the committee should focus on readjustment problems of combat veterans in all wars and all conflicts. We also recommend that the makeup of the statutorily empowered advisory committee be similar to the existing committee.

Many veterans are diagnosed by VA physicians as meeting all six criteria for PTSD but, having failed to receive a service-connected disability rating, they are not considered Category A veterans and, therefore, are denied treatment in VA medical centers. Nonservice-connected Category A, B and C veterans with diagnosed PTSD are subject to receiving VA treatment on a space and resource available basis. Given budgetary constraints evident throughout the VA medical care system, these veterans suffering from post-traumatic stress disorder could be denied care due to the means test criteria. The American Legion feels that the VA has an obligation to these veterans to render prompt and adequate treatment.

Mr. Chairman, that concludes our statement.

[The prepared statement of the American Legion appears at p. 165.]

Mr. ROWLAND OF GEORGIA. Thank you, Mr. Buxton.

Mr. Bollinger.

STATEMENT OF JOHN C. BOLLINGER, ASSOCIATE LEGISLATIVE DIRECTOR, PARALYZED VETERANS OF AMERICA

Mr. BOLLINGER. Thank you, Mr. Chairman, and thank you for inviting PVA to testify today. We certainly endorse Mr. Jontz' bill, H.R. 3037, and wish to thank you for your interest in the well-being of veterans that suffer from PTSD.

Clearly, there are significant unmet needs which exist in VA's PTSD program. Since PTSD is generally chronic in nature, we be-

lieve the lifetime prevalence of the disorder necessitates expanded availability of PTSD professional help, both now and in the future.

Before I talk about some of the specifics of the bill, I would like to make two general comments about some longstanding concerns PVA has had about PTSD treatment. First, we firmly believe that such care should be provided to veterans of other wars and conflicts in the same manner that it is provided to Vietnam veterans. We know, for example, that World War II veterans, Korean veterans, and veterans of other conflicts have come to Vet Centers and have either been turned away or perhaps treated without authority because VA does not have the authority to treat them. So we believe the absence of such authority leaves an enormous gap in what should be VA's obligation to provide care on an equitable basis for all those who suffer from PTSD.

Second, I would like to emphasize that our support of legislation to extend outpatient services and extended care to all Category A veterans does include the availability of professional care for those with PTSD. It certainly has been, and continues to be, our intention to include such care in any expansion of outpatient treatment.

Regarding the bill, we certainly endorse the expansion of the number of Vet Centers and inpatient treatment facilities. The bill also states that the Secretary shall establish the new Vet Centers in cities that don't currently have them. Although in most cases we think this would probably best serve most eligible veterans well, we think some flexibility should be given to the Secretary to improve or expand services in certain urban areas that may need another Vet Center in addition to PTSD services already provided there.

Regarding section 4 of the bill, we might prefer to see—and we believe it might be more cost effective—to open and staff a Vet Center rather than to contract out services to private facilities and therapists. We recognize the need for certain contract services in the case of contracting services for treatment and rehabilitation of PTSD patients as addressed in section 7 of your bill. Experts in the community would provide care in half-way houses, psychiatric residential treatment centers, and other places where there is an absence of VA professional care. We endorse the pilot program approach to this concept.

We do believe, however, that adequate resources for VA's Vet Centers, VA's inpatient PTSD care, and a coordinated case-managed approach to vocational rehabilitation involving the Veterans Benefits Administration should be the primary focus of a comprehensive PTSD treatment program.

I will now conclude my remarks and will certainly answer any questions I can. Thank you.

[The prepared statement of John C. Bollinger appears at p. 174.]

Mr. ROWLAND OF GEORGIA. Thank you very much.

Mr. Gorman.

STATEMENT OF DAVID W. GORMAN, ASSISTANT NATIONAL LEGISLATIVE DIRECTOR FOR MEDICAL AFFAIRS, DISABLED AMERICAN VETERANS

Mr. GORMAN. Thank you, Mr. Chairman. It's a pleasure to be here, and I would like to thank the subcommittee for the timely scheduling of this hearing and also certainly to acknowledge and thank Mr. Jontz for his interest in the well-being of Vietnam veterans suffering with PTSD.

A lot has been said this morning. I think the thing to keep in mind first and foremost is that post-traumatic stress disorder is, by its nature, a service-connected disability. It's a combat-induced condition and I don't think we should lose sight of that.

Generally, we are also supportive of your bill, Mr. Jontz, H.R. 3037. The details of our support and our concerns, are outlined in our written testimony and I won't go through those at this time.

Like my colleagues, I would like to indicate our support for the expanded eligibility for the furnishing of readjustment counseling services to veterans of all wars. You can look back and see that veterans of previous wars have been diagnosed as having shell shock, battle neurosis, war fatigue, and what it all boils down to I think is the same thing, that is, it recognizes by a different name post-traumatic stress disorder.

With that, I would like to conclude my remarks again by just stating our general support of the bill, and our written statement outlines that support. Thank you.

[The prepared statement of David W. Gorman appears at p. 178.]

Mr. ROWLAND OF GEORGIA. Thank you, Mr. Gorman.

Mr. Egan.

STATEMENT OF PAUL S. EGAN, LEGISLATIVE DIRECTOR, VIETNAM VETERANS OF AMERICA, INC.

Mr. EGAN. Thank you, Mr. Chairman. I suppose being the last witness on the last panel of a rather long hearing makes it somewhat challenging to find something to say that hasn't already been said a variety of times already. But I think I will make a couple of comments on some of the testimony that the subcommittee has heard already this morning.

First of all, I was really very surprised and somewhat disappointed to hear the witness from the American Psychiatric Association express their view that they're not particularly supportive of the Vet Center program. I'm not sure if the subcommittee recalls this, but they have been very strongly in support of the Vet Center program for the last 11 years.

We have known for some time that there's a turf struggle going on within the VA, and it's a turf struggle basically over ownership of PTSD treatment and PTSD treatment resources. The struggle is waged between the Readjustment Counseling Service, which operates the Vet Centers, and the hospital part of the shop. I hope that what we're seeing with the APA's testimony this morning isn't the enlistment of public and professional organizations to further carry out that turf battle, because obviously, with the size and breadth of the PTSD problem among veterans, they're the ones that are getting caught in the middle.

As for the VA's testimony, it wasn't particularly surprising to hear them oppose the bill, based on their contention that they already have the authority to do the things that are called for in the legislation. But that argument rings rather hallow since the issue isn't really whether they have the authority; the issue is whether they have been able to see their way clear to exercise that authority.

We have known now for 18 months since the RTI study was released, and we've known for quite some time since the Legion's experience study was released, recently in March there was a twin study—Dr. Niles has just completed his study—we've known for a long time the problem is large. We have known for a long time that something has to be done about it. The appalling fact is the VA has been very, very slow to respond. It is especially appalling because this is not only a service-related disability, it's a combat-related disability. One wonders whether the VA has lost sight completely of its mission to take care of service-related problems.

The entire cost of the Vet Center program today is a mere $47 million. That's not an exorbitant price to pay for the services that are being effectively provided by the Vet Center program. I'm not sure what the exact cost of inpatient PTSD units are, but judging by the first year cost of H.R. 3037, which is only $7 million, it can't be that much. So raising resources as an obstacle to this legislation is also really a false argument.

Given the size of the problem, we have to look at what are the tools that are best available and can best be utilized to address the problem. The tools we have for outpatient treatment, and the Vet Center program provides the lion's share of outpatient treatment that is provided by the VA—and it does a good job of it; that's pretty well documented. We know the Vet Centers work. We also know there are a lot of mid-sized cities and rural areas in the country that are completely unserved by the Vet Center program. So it's logical to expand that program.

On an inpatient basis, there are only 16 inpatient PTSD units, with four more to come. With waiting periods for admission are up to 2 years in some places, that's obviously too much time. It certainly isn't asking too much to ask that there be one inpatient PTSD unit in each State. But the 16 that are currently operating aren't particularly well coordinated. That's partly a result of the fact that the VA Central Office hasn't really issued any clear indication that this problem is a priority matter.

You see some inpatient units that are operating as the fiefdoms of whoever is the clinical director of the program. Others of them are masquerading as inpatient PTSD units but really are just general psychiatry.

One of the ways in which that can be improved upon, which is also included in Mr. Jontz' bill, is to establish one of these units as an inpatient PTSD treatment research unit. It can serve as a conduit through which coordination of the other units can be managed but can also begin to develop the kinds of treatments that work best. We've seen a lot of research on the pathologic content of PTSD but precious little on what kinds of treatment works. I think this bill would go a long way in that direction.

Finally, Mr. Chairman, we would agree with our colleagues from the Legion in expressing some reservations about the specific language of the legislation, placing in statute the Advisory Committee on the Readjustment of Vietnam Veterans. We think that committee works well, it should be continued as is, but the importance of putting it in statute I think is very great, and the best evidence of that is the failure of that committee to be able to meet this last May.

I see that the red light is on. I will wrap it up there.

[The prepared statement of Paul S. Egan appears at p. 184.]

Mr. ROWLAND OF GEORGIA. Thank you very much.

Let me ask you a question about PTSD, the etiology of it. I had thought about PTSD as being a reaction to a stressful situation, regardless of where that situation may have happened. Mr. Gorman, you and Mr. Egan both state that it is combat-induced. Is that the way that your groups look at it, as being combat induced and not coming about through some other stressful situation?

Mr. GORMAN. Mr. Chairman, I didn't intend to make that a blanket statement, that PTSD can only be diagnosed as resulting from a combat-related source. Certainly I don't believe that and the DAV would put that forward as a position. I think in the majority of cases that we're talking about here within the VA and the treatment of PTSD, that that is, in fact, the case.

Mr. EGAN. I would echo those comments.

I'm recalling the scoring method that the Legion used in determining, of the Legionnaires that were sampled, as to which of them had the greatest likelihood of having PTSD. There were different kinds of experiences. Probably the Legion could speak better to this than I can. But there were different kinds of experiences. Most of them were combat; some of them not so much. But those individuals who had the highest scores—that is, who were likely to have had the highest stress—had the highest incidence of PTSD.

There's no doubt that combat stress causes PTSD, but it certianly is also true that there are other stressors out there short of combat that also can end up with the same phenomenon.

Mr. ROWLAND OF GEORGIA. Very good. Thank you.

I have some other questions that I will submit for the record, but let me recognize Mr. Jontz at this point.

Mr. JONTZ. I want to thank all the witnesses for their support of the legislation, and also for a number of helpful comments. Mr. Buxton, your concern about the composition of the committee I think is well-taken, and other comments for improvements I also think can be incorporated.

I do just have one question for Mr. Egan. One of the provisions in the bill which has not been discussed at great length, but which was the subject of some modest criticism, was the contract care provision. I understand that part of the problem is that there's been a wide fluctuation the amount of funds for this and that there would be some purpose served by attempting to stabilize the amount of funds that that would help in the treatment, from the standpoint that there would be a more dependable source of funding.

Perhaps you or others, if someone wishes to comment on this matter, can give the committee just a little bit of information about

the existing nature of the contract care that is provided and what some of the problems have been that we ought to be looking at in writing this legislation.

Mr. EGAN. Well, again, it's because the Vet Center program is limited that it's needed, that the contract provider program is needed. These are contract providers that are usually located in rural areas of the country where there is no Vet Center, where there is no VA medical center, where there is no outpatient clinic or other type of clinic.

The budget for the contract provider program has fluctuated rather wildly over the years. Now, for the contract provider interested in doing some work with veterans, 1 year there's money in the budget to pay him for the work that he does, and the next year there isn't. So it raises an issue of trust in the VA on the part of the contract provider, and when the funds are reduced, if the contract provider is still interested in staying with the program because he's still interested in working with veterans, usually what happens is that you move from individual counseling sessions to group counseling session, which sometimes can be as effective as individual sessions, but not always. But by cutting off the funds, you're cutting off the number of providers there are and, therefore, cutting off or reducing the availability of some kind of treatment resources in rural areas. So stability for that particular program I think is long overdue and certainly a welcome part of that bill.

Mr. JONTZ. Thank you, Mr. Chairman.

Mr. ROWLAND OF GEORGIA. Thank you very much. I want to thank all of you very much for being here today. It has been a long hearing and you've been very patient.

The subcommittee stands adjourned.

[Whereupon, at 1:00 p.m., the subcommittee was adjourned.]

APPENDIX

101ST CONGRESS
1ST SESSION

H. R. 3037

Providing for the expansion of the services the Department of Veterans Affairs provides to veterans suffering from post-traumatic stress disorder, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 27, 1989

Mr. JONTZ (for himself, Mr. EVANS, Ms. LONG, Mr. BONIOR, Mr. LANCASTER, Mr. KENNEDY, Mr. GEJDENSON, Mr. NAGLE, Mr. WISE, Mr. DEFAZIO, Mr. MORRISON of Connecticut, Mr. BROWN of California, Mrs. UNSOELD, Mr. MCCLOSKEY, Mr. COLEMAN of Texas, Mrs. LOWEY of New York, Mr. MRAZEK, Mr. WEISS, Mr. RICHARDSON, Mr. HAYES of Illinois, Mr. PALLONE, Mr. DELLUMS, Mr. STAGGERS, Mr. FAUNTROY, Mr. HOCHBRUECKNER, Mr. FEIGHAN, Mr. JOHNSON of South Dakota, Mr. LAUGHLIN, Mr. OWENS of Utah, Mr. POSHARD, Mr. AUCOIN, Mr. SAWYER, Mr. LELAND, Ms. SLAUGHTER of New York, Mr. EDWARDS of California, Ms. KAPTUR, Mr. TOWNS, Mr. LEWIS of Georgia, Mr. OWENS of New York, Mr. FRANK, Ms. PELOSI, Mr. MOODY, Mr. ROSE, Mr. BRUCE, Mr. BORSKI, and Mr. BERMAN) introduced the following bill; which was referred to the Committee on Veterans' Affairs

A BILL

Providing for the expansion of the services the Department of Veterans Affairs provides to veterans suffering from post-traumatic stress disorder, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Veterans PTSD Treatment and Psychological Readjustment Act of 1989".

SEC. 2. FINDINGS.

The Congress finds that—

(1) over 800,000 Vietnam-era veterans suffer from post-traumatic stress disorder (hereinafter in this Act referred to as "PTSD");

(2) only 10 percent of Vietnam-era veterans suffering from PTSD have used the programs offered by the Department of Veterans Affairs for the treatment of PTSD;

(3) expanding the vet center program, inpatient PTSD treatment, and other PTSD treatment programs would be effective methods of serving more veterans suffering from PTSD;

(4) providing constant funding for the Readjustment Counseling Program of the Department of Veterans Affairs would be beneficial in treating veterans suffering from PTSD; and

(5) coordinating and developing a standard PTSD treatment program would greatly enhance the Department of Veterans Affairs' ability to more effectively treat and rehabilitate veterans suffering from PTSD.

SEC. 3. EXPANSION OF THE NUMBER OF PTSD TREATMENT FACILITIES.

(a) NUMBER OF VET CENTERS AND INPATIENT TREATMENT UNITS.—The Secretary of Veterans Affairs (hereafter in this Act referred to as the "Secretary") shall—

(1) subject to subsection (b), increase the number of vet centers existing on the date of enactment of this Act by not less than 20 additional units by December 31, 1991, and by not less than an additional 20 units by December 31, 1994; and

(2) increase the number of inpatient post-traumatic stress disorder treatment facilities existing on the date of enactment of this Act by not less than 15 additional units by December 31, 1991, and by not less than an additional 15 units by December 31, 1994.

(b) LOCATIONS OF VET CENTERS.—In carrying out subsection (a)(1), the Secretary shall establish vet centers in cities that, as of the date of enactment of this Act, do not have vet centers.

(c) DEFINITION OF VET CENTER.—As used in this section, the term "vet center" has the meaning given that term in section 612A(i)(1) of title 38, United States Code.

SEC. 4. FUNDING FOR CONTRACTS FOR THE PROVISION OF PTSD TREATMENT.

Of the amount available to the Secretary in fiscal year 1990 for the provision of services to veterans for the treat-

ment of PTSD, $10,000,000 shall be allocated for contracts with private facilities and therapists under section 612A(e) of title 38, United States Code.

SEC. 5. USE OF SCHOLARSHIP AND TUITION REIMBURSEMENT PROGRAMS FOR MENTAL HEALTH PROFESSIONALS.

In administering the Health Professionals Educational Assistance Program (chapter 76 of title 38, United States Code), the Secretary shall seek to encourage the participation of individuals in the program who desire to become psychiatrists, psychologists, and psychiatric nurses specializing in the treatment of PTSD. The Secretary shall consider designating, pursuant to section 4312(b)(3) of title 38, United States Code, additional fields of education or training that may be beneficial for the comprehensive treatment of veterans suffering from PTSD.

SEC. 6. ADVISORY COMMITTEE ON READJUSTMENT OF VETERANS.

(a) ESTABLISHMENT OF ADVISORY COMMITTEE.—Subchapter II of chapter 3 of title 38, United States Code, is amended by adding at the end the following new section:

"§ 225. Advisory Committee on Readjustment of Veterans

"(a)(1) The Secretary shall establish an advisory committee to be known as the Advisory Committee on Readjust-

ment of Veterans (hereinafter in this section referred to as the 'Committee').

"(2) Except as provided by paragraph (3), the members of the Committee shall be appointed by the Secretary from the general public and shall include individuals who are recognized authorities in fields pertinent to the social, psychological, economic, or educational readjustment of veterans, who are not current employees of the Department of Veterans Affairs, and who have preferably been awarded a campaign or expeditionary medal from the Armed Forces. The Secretary shall appointment at

"(3) The Committee shall include, as ex officio members—

"(A) the Assistant Secretary of Labor for Veterans Employment and Training (or a representative designated by the Assistant Secretary;

"(B) the Assistant Secretary of Defense for Manpower (or a representative designated by the Assistant Secretary);

"(C) an appropriate official, appointed by the Secretary, from each of the Small Business Administration, the Office of Personnel Management, and the Department of Education; and

"(D) at least five members, appointed by the Secretary, who are members of veterans service organiza-

tions chartered by an Act of Congress that have an interest in the treatment of PTSD, except that not more than one member may be from the same organization.

"(4) The Secretary may invite representatives of departments and agencies of the United States, other than those referred to in paragraph (3) of this subsection, to participate in the meetings and other activities of the Committee.

"(5) The Secretary shall determine the term of service and pay and allowance of members of the Committee appointed under paragraph (2) of this subsection, except that the term of service of any such member may not exceed three years. The Secretary may reappoint any such member for additional terms of service. The Secretary shall determine the number of members, except that such number may not exceed 20 nor be less than 12.

"(6) The Committee shall meet once every four months.

"(b)(1) The Secretary shall, on a regular basis, consult with and seek the advice of the Committee with respect to—

"(A) the administration of benefits by the Department of Veterans Affairs for post-Vietnam era veterans and veterans of any war, but with particular emphasis on Vietnam era veterans; and

"(B) reports and studies pertaining to post-Vietnam era veterans and veterans of any war, but with particular emphasis on Vietnam era veterans; and

"(C) the needs of post-Vietnam era veterans and veterans of any war with respect to compensation, health care, readjustment, outreach, and other benefits and programs administered by the Department.

"(2) Not later than July 1 of each year, the Committee shall submit to the Secretary a report on the programs and activities of the Department that pertain to the social, economic, educational, and psychological readjustment of veterans. Each report shall contain—

"(A) an assessment of the needs of post-Vietnam era veterans of any war with respect to compensation, health care, readjustment, outreach, and other benefits and programs administered by the Department of Veterans Affairs;

"(B) a review of the programs and activities of the Department of Veterans Affairs designed to meet such needs;

"(C) such recommendations (administrative and legislative) as the Committee considers appropriate; and

"(D) such other matters as the Committee considers appropriate.

"(3) Within 60 days after receiving each such report, the Secretary shall submit to the Congress a copy of the

report together with any comments concerning the report that the Secretary considers appropriate.

"(4) The Secretary shall submit with each annual report, submitted to the Congress pursuant to section 214 of this title, a summary of all reports and recommendations of the Committee submitted to the Secretary since the previous annual report of the Secretary submitted pursuant to such section.".

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 3 of such title is amended by inserting after the item relating to section 223 the following:

"225. Advisory Committee on Readjustment of Veterans.".

SEC. 7. PILOT PROGRAM FOR TREATMENT OF PTSD.

(a) ESTABLISHMENT OF PROGRAM.—Subchapter II of chapter 17 of title 38, United States Code is amended by adding at the end the following new section:

"§ 620C. Treatment and rehabilitation for post-traumatic stress disorder; pilot program

"(a)(1) The Secretary, in furnishing hospital, nursing home, and domiciliary care and medical and rehabilitative services under this chapter, may conduct a pilot program under which the Secretary may contract for care and treatment and rehabilitative services in halfway houses, therapeutic communities, psychiatric residential treatment centers, and other community-based treatment facilities for eligible veterans suffering from post-traumatic stress disorder. Such

pilot program shall be planned, designed, and conducted by the Chief Medical Director, with the approval of the Secretary, so as to demonstrate any medical advantages and cost effectiveness that may result from furnishing such care and services to veterans with post-traumatic stress disorder in contract facilities as authorized by this section, rather than in facilities over which the Secretary has direct jurisdiction.

"(2) Before furnishing such care and services to any veteran through a contract facility as authorized by paragraph (1) of this subsection, the Secretary shall approve (in accordance with criteria which the Secretary shall prescribe by regulation) the quality and effectiveness of the program operated by such facility for the purpose for which such veteran is to be furnished such care and services.

"(b) The Secretary, in consultation with the Secretary of Labor and the Director of the Office of Personnel Management, may take appropriate steps to (1) urge all Federal agencies and appropriate private and public firms, organizations, agencies, and persons to provide appropriate employment and training opportunities for veterans who have been provided treatment and rehabilitative services under this title for post-traumatic stress disorder and have been determined by competent medical authority to be sufficiently rehabilitated to be employable, and (2) provide all possible assistance to

the Secretary of Labor in placing such veterans in such opportunities.

"(c) Upon receipt of an application for treatment and rehabilitative services under this title for post-traumatic stress disorder from any individual who has been discharged or released from active military, naval, or air service but who is not eligible for such treatment and services, the Secretary shall—

"(1) provide referral services to assist such individual, to the maximum extent practicable, in obtaining treatment and rehabilitative services from sources outside the Department; and

"(2) if pertinent, advise such individual of such individual's rights to apply to the appropriate military, naval, or air service and the Department for review of such individual's discharge or release from such service.

"(d)(1) Any person serving in the active military, naval, or air service who is determined by the Secretary concerned to have post-traumatic stress disorder may not be transferred to any facility in order for the Secretary to furnish care or treatment and rehabilitative services for such disability unless such transfer is during the last thirty days of such member's enlistment period or tour of duty, in which case such care and services provided to such member shall be provided as if such

member were a veteran. Any transfer of any such member for such care and services shall be made pursuant to such terms as may be agreed upon by the Secretary concerned and the Secretary of Veterans Affairs, subject to the provisions of the Act of March 4, 1915 (31 U.S.C. 686).

"(2) No person serving in the active military, naval, or air service may be transferred pursuant to an agreement made under paragraph (1) of this subsection unless such person requests such transfer in writing for a specified period of time during the last thirty days of such person's enlistment period or tour of duty. No such person transferred pursuant to such a request may be furnished such care and services by the Secretary beyond the period of time specified in such request unless such person requests in writing an extension for a further specified period of time and such request is approved by the Secretary.

"(e) The Secretary may not furnish care and treatment and rehabilitative services under subsection (a) of this section after the last day of the fifth fiscal year following the fisal year in which the pilot program authorized by such subsection is initiated.

"(f) Not later than March 31, 1993, the Administrator shall report to the Committees on Veterans' Affairs of the Senate and House of Representatives on the findings and recommendations of the Secretary pertaining to the operation

through September 30, 1992, of the pilot program authorized by this section.

"(g) The authority of the Secretary to enter into contracts under this section shall be effective for any fiscal year only to such extent or in such amounts as are provided in appropriation Acts.".

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 17 of such title is amended by inserting after the item relating to section 620B the following:

"620C. Treatment and rehabilitation for post-traumatic stress disorder; pilot program.".

SEC. 8. RESEARCH PROGRAM FOR TREATMENT OF PTSD.

The Chief Medical Director of the Department of Veterans Affairs shall conduct, through the National Center on Post-Traumatic-Stress Disorder, a research program relating to the treatment of PTSD. The purpose of the program shall be to—

(1) determine the most effective modalities of treatment for PTSD in both inpatient and outpatient settings; and

(2) to coordinate and standardize the treatment of PTSD in the facilities of the Department treating veterans suffering from PTSD.

Statement of
Honorable John Paul Hammerschmidt
Ranking Minority Member

Subcommittee on Hospitals & Health Care

Hearing Regarding PTSD and Clozaril
June 28, 1990

Mr. Chairman and members of the subcommittee, it is a pleasure to be here today as we address the issue of post-traumatic stress disorder and the perplexing issue of access of certain veteran patients to receive the atypical antipsychotic drug know as Clozaril.

Today the subcommittee will review the various services and programs provided by the Department of Veterans Affairs in order to care for veterans suffering from PTSD. It is important to point out that the Department is a recognized leader in the development of clinical treatment programs which have significantly increased the body of knowledge regarding PTSD and the quality of care received by veterans with PTSD. The Department is deserving of praise in this regard.

However, it is well known that the Department's psychiatric patient workload has increased significantly over the last five years. There were 5,377 inpatient discharges in 1984 and 12,750 in 1989. Unfortunately, like the Department's medical care account in general, funding levels have not been sufficient to support this increase in both inpatient and outpatient treatment episodes.

In addition to an increased demand by veteran patients with PTSD, the cost of providing the necessary specialized care has also risen. The Department has responded by decreasing length of stay in hospital settings, while at the same time increasing its reliance on outpatient methods for care.

This subcommittee should evaluate the effects these changes have had on the ability of the Department to provide high quality care to veterans with PTSD. And we should, with an ever watchful eye on limited resources, decide if improvements or expansions to the Department's current methods of care are necessary.

H.R. 3037, introduced by my colleague Mr. Jontz, contains several legislative proposals designed to expand PTSD programs. The subcommittee today will examine this subcommittee today will examine this legislative proposal as well.

Finally, Mr. Chairman, I appreciate the opportunity for the subcommittee to address the Department's recent attempts to make available to its veteran patients Clozaril, a newly marketed and very promising drug. As you know, the cost of this drug is prohibitive due to its packaging. Conservative estimates place the cost to the Department at $18 million per year.

In fact this may raise legal questions due to the manufacturer's refusal to sell the drug to the VA unless the Department also agrees to buy its Clozaril Patient Monitoring System.

Let me make it perfectly clear that this subcommittee has always concerned itself with situations which impede veterans' access to the medical care and services they need. At the same time, we have expended considerable time and attention to ensuring that the care veterans receive is of the highest quality and is cost-effective. That is the bottom line on the Clozaril issue.

I would like to include with my statement an article by Dr. Norman Canterbury, Executive Vice President, Arkansas Pharmacists Association, concerning Clozaril.

Mr. Chairman, the Department of Veterans Affairs has been in the forefront of the Clozaril issue for quite some time. They were able to provide committee staff a detailed briefing in January. From the very beginning the VA has taken an active role in the resolution of this issue and has done a superb job of advocating on behalf veterans with schizophrenic disorder. In particular, the efforts of Dr. Larry Lehman, VA's Associate Director for Psychiatry and Ms. Louise Rodriguez of VA's Pharmacy Service deserve recognition.

Mr. Chairman, I join you in welcoming today's distinguished panel of witnesses and thank them for being here.

THE EXEC SPEAKS

SANDOZ BY-PASSES PHARMACY

By Norman Canterbury, P.D.
Executive Vice President
Arkansas Pharmacists Association

The Sandoz decision to circumvent the community pharmacist in dispensing their new drug, Clozaril, has been a stinger to pharmacy. The decision apparently was a Sandoz corporate decision without consultation with pharmacy leadership, viewing the outcry from national pharmacy leadership in addition to the state and local disgust voiced by pharmacists.

The Clozaril Patient Management System (CPMS) was designed according to Sandoz with the patient's best interest in mind, but Sandoz mistakenly assumed that the patient belongs to them and has no autonomy to exercise in this situation. Who does the patient belong to? According to this decision, the patient is not relative to their chosen local physician or pharmacists, but rather is a pawn of the drug manufacturer.

It is important to note that Sandoz has developed a very worthy drug that should improve the quality of life for an unresponsive number of very sick people. It is also documented that this drug regimen produces a very real risk of agranulocytosis which is not taken lightly by anyone. Even noting this, there is no tolerance for the aristocratic and even arrogant appearing decision by Sandoz management that they are the sole guardian of the patient in the use of this drug.

Jacques Rojoange, President of Sandoz, stated that he was particularly distressed to hear Dr. John Gans, President of APhA, state that this management by Sandoz was an example of corporate irresponsibility. I agree with Dr. Gans, but I also see their decision as a cavalier action designed to brush pharmacy aside without due consideration of the pharmacists' professional capability in the care of their patients.

Why is there such an outcry from pharmacy? Are we going to let the drug manufacturers determine the role of the pharmacist and when he is included or excluded from the care of the patient? Are we going to allow another entity to assess our capability? Finally, are we going to stand by and let a manufacturing autocrat take our patients? The HMO's and some managed care entities are doing this already. Anything new or different, such as this action, can be the beginning of a larger movement by others. Has Sandoz initiated the first step that will lead to similar actions by other companies?

This is a time when drug companies and pharmacy should be trying to overcome our differences. An action like this by Sandoz increases the suspicion by pharmacy that they are only ultimately concerned about themselves.

The new twist in this Sandoz delivery system is that Sandoz names the participants, as well as the price. The cost of delivery to the patient, I assume, will include the drug cost, lab fees, and providers charges. How would this be billed to Medicaid under the prescription drug program? The estimated cost for this package is $9,000 per year per patient. Expensive? Yes! Necessary? No!

I have been telling Arkansas pharmacists for some time now that things are changing, but never expected decisions like this. There are going to be more drugs in the future, by their very nature, that are going to require special handling, adjustments or precautions on the part of pharmacy. Pharmacy must adapt quickly, even instantly, and we can. You must continue to adjust your thinking to the conviction that we must do whatever is necessary for the care of our patient. We must be willing to convert our thinking from "here's what it's been" to "this is what we've got to do." This is an evolutionary era that will probably have no real end point. I can see health care providers, pharmaceuticals, and drug delivery systems being at the center of this change. The problem with Clozaril is not that it is part of this change, instead Sandoz erred in making an important decision relating to Pharmacy that is part of this change.

It is important now that Sandoz make the necessary changes to correct this situation.

Arkansas Pharmacists Association
417 South Victory • Little Rock, Arkansas 72201 • 372-5060

Norman Canterbury, P.D.
Executive Vice President

A RESOLUTION

WHEREAS, Sandos Pharmaceuticals has developed and secured approval for marketing their new drug, Clozaril, which will afford a major contribution in the treatment of selected severely ill schizophrenic patients, and

WHEREAS, the necessity for a very closely controlled professional monitoring system is recognized by all for the involved patient under this treatment, and

WHEREAS, Sandos Pharmaceuticals has circumvented the local pharmacist in the evaluation, monitoring, and care of the pharmacist's patient, and

WHEREAS, Sandos has neglected to work with the profession of pharmacy to create the professional patient monitoring system important for the welfare of this patient.

BE IT THEREFORE RESOLVED, that the Arkansas Pharmacists Association expresses it profound and deep-felt distress and dissatisfaction with the Sandos Clozaril Patient Management System (CPMS), and we do now urge and implore Sandos to work with the profession of pharmacy to solve this eminent and serious dilemma.

ADOPTED, by the Arkansas Pharmacists Association in annual convention assembled in Little Rock, Arkansas on the Ninth day of June, 1990.

Attest:

Norman Canterbury, P.D.

Norman Canterbury, P. D.
Executive Vice President

American Pharmaceutical Association
APhA
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The National Professional Society of Pharmacists

ISSUE BRIEF

RESTRICTED DISTRIBUTUION OF CLOZAPINE (Clozaril) THROUGH THE CLOZARIL PATIENT MANAGEMENT SYSTEM (CPMS)

BACKGROUND:

In September, 1989, the Food and Drug Administration issued a letter of approvability to Sandoz Pharmaceuticals for its drug clozapine (Clozaril). Clozapine, a dibenzodiazepine, is indicated for the treatment of severe, refractory schizophrenia in patients who fail to respond adequately to standard antipsychotic drug treatment. A primary adverse effect of the medication is agranulocytosis, a potentially fatal blood dyscrasia resulting from suppression of production of white blood cells. The problem was identified in clinical trials with the drug in the early 1970's, resulting in increased monitoring. Relatively few deaths have occurred due to the drug since 1977, according to the manufacturer. Most recent data on the occurrence of non-fatal marrow suppression show a rate of approximately 1%. With proper monitoring and discontinuation of therapy when marrow suppression becomes significant, the problem is generally reversible.

In seeking FDA approval for the drug, Sandoz proposed a restricted distribution system for clozapine to monitor for this specific adverse effect. The system, known by the service-marked title of "Clozaril Patient Management System" (CPMS), is an exclusive contractual arrangement between Sandoz Pharmaceuticals, the Caremark Home Health Care Division of Baxter Healthcare, and Roche Biomedical Laboratories. Essentially, the system provides for the distribution of weekly supplies of clozapine ONLY in conjunction with a weekly blood sample collection and determination of the white blood cell (WBC) count. Caremark is the sole source of supply for the medication, both for ambulatory patients, and for hospitals seeking to obtain the medication for use in inpatients. Charges for clozapine are bundled with charges for the home care, phlebotomy and laboratory monitoring services, and have been set at $172.00 per week, regardless of dose, which may range from 100-900 mg per day.

While CPMS was not a condition of the FDA for drug approval, reference to it is contained in the official product labeling for clozapine under the "How Supplied" section. National pharmacy organizations became fully aware of the proposed system at approximately the time of approval of the drug's labeling, and began activities (see chronology), both individually and collectively to address the problem. Clozapine became commercially available in the U.S., through CPMS, on Feb 5, 1990.

STATUS:

The restricted distribution and bundled charges program for clozapine, CPMS, continues in place at this time. Sandoz' position remains that a restricted distribution system is necessary to adequately monitor for and prevent the occurrence of agranulocytosis. CPMS does not address any of the other adverse effects (seizures, neuroleptic malignant syndrome, tardive dyskinesia), drug interactions or other potential problems associated with the medication.

--more--

APhA's POSITION:

APhA policy opposes limited distribution of any pharmaceutical product since such plans prevent the involvement of pharmacists in patient care. The Association won an important court victory over the Food and Drug Administration in 1973 when FDA attempted through regulation to restrict the distribution of methadone to hospital pharmacies. It should be noted that the clozapine situation is substantially different, in that the restricted system has been developed by the manufacturer of the product. However, APhA has recently been successful in removing restrictions imposed by Lilly on the distribution of its human growth hormone product.

APhA's opposition to CPMS is based not only on policy grounds, but on the firm conclusion that the system is clinically, scientifically and economically unjustifiable. Specifically:

- the system clearly interferes with established relationships of pharmacists, patients and physicians;
- the incidence of clozapine-induced agranulocytosis is insufficiently different from, and in some cases is less than, other medications which may cause the problem. These medications are currently managed effectively by pharmacists and physicians in carrying out their patient care responsibilities;
- other pharmaceutical manufacturers of products with severe adverse effects have worked effectively with pharmacists and physicians to prevent drug related problems, rather than by-passing them;
- FDA did not require CPMS as a condition for drug approval;
- CPMS needlessly increases the costs of clozapine therapy. At approximately $9000 per patient per year, CPMS results in needless duplication of resources for many patients, who already receive pharmacy, laboratory and other care and services within the current system.

APhA's ACTIVITIES:

The chronology outlined on the following page summarizes the activities of APhA, and other pharmacy organizations, on the clozapine issue. Patient safety is of critical importance to APhA and to its member pharmacists. Nevertheless, we remain unconvinced that the side effect profile of clozapine justifies the existence of CPMS. In fact, the splitting of care between multiple pharmacy care providers, and the focus of CPMS on a single side effect to the exclusion of the patient's overall medication response, presents substantial risks of its own.

APhA remains committed to the dismantling of CPMS. Our opposition is based on policy, on the specific data of this case and on the basis of the demonstrated expertise and capabilities of pharmacists and physicians to effectively and safely manage complex and potentially dangerous drug therapies. We will continue to work with pharmacy and medical organizations, FDA, the Congress and others to achieve that goal.

Honorable Bob McEwen
Subcommittee on Hospitals & Health Care
Hearing on Mental Health Services to
Veterans with PTSD and H.R. 3037

Thank you Mr. Chairman.

I would like to commend you, Mr. Chairman for scheduling today's hearing. It has been a while since we were able to focus the proceedings of an entire hearing on the issue of veterans mental health care, and clearly this is an important matter.

I think many of us occasionally feel frustrated in our efforts to serve the subcommittee -- frustrated by the many complicating issues that surround mental health diagnoses and treatment. We all want to do what is right for the veterans and it is a real challenge because most of us do not have a medical background. Dr. Rowland is a notable exception.

But thankfully, our committee -- and our nation -- continue to learn more about mental health and mental health problems, and how they are manifested in our veterans. I look forward to learning a good deal more today.

I think we are all hopeful that we can continue to address mental health issues in ways that will serve the veteran, which will ease or eliminate the other problems that often arise from mental illnesses, and which will benefit the American people as a whole.

The truth is: many people have benefitted from research and treatment techniques which originated in the veterans health care system, and I look for that to continue.

There already exists one especially promising form of drug therapy which has proven extremely effective for some sufferers of schizophrenia. I am particularly eager to explore that issue today, and we have witnesses with us this morning who can discuss that issue.

I look forward to hearing from them, and would like to yield so we may hear their testimony. Thank you all for coming today.

DAVID PRYOR, ARKANSAS, Chairman
JOHN GLENN, OHIO
BILL BRADLEY, NEW JERSEY
QUENTIN N. BURDICK, NORTH DAKOTA
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United States Senate
SPECIAL COMMITTEE ON AGING
WASHINGTON, DC 20510-6400

STATEMENT OF SENATOR DAVID PRYOR (D-ARK)

Chairman, U.S. Senate Special Committee on Aging
before the U.S. House of Representatives
Committee on Veterans Affairs

June 28, 1990

Subcommittee on Hospitals and Health Care

Good morning, Mr Chairman and members of the Committee. The purpose of this statement is to express my outrage over the blatant profit maximization scheme developed by the Sandoz Pharmaceuticals Corporation for the sale and distribution of its antischizophrenic drug Clozaril in this country.

Mr. Chairman, before I proceed let me apologize for being unable to deliver this statement in person before the Committee. I had made a previous commitment to hold a workshop on the upcoming reauthorization of the Older Americans Act, but I wanted to be sure that the Committee was aware of my position on the issue, and the legislative initiative that I have developed which will address this unacceptable situation.

I commend the Chairman for calling this hearing to seek real answers to the questions about Clozaril and why Sandoz will not allow health care institutions to provide the product through the normal channels of distribution. After several meetings with the principal companies involved in this scenario, I am not satisfied that we have heard the real answers to our questions about the need for this scheme, and the real motivation behind its development.

As you are aware, Mr. Chairman, I have been very concerned about the high cost of prescription drugs since I came to Congress, first as a member of the House and now as a member of the Senate. After assuming the Chairmanship of the Senate Special Committee on Aging in 1989, I made prescription drug prices a top priority: I wanted to know why drug prices were so high, and why we cannot seem to get them under control. Two investigations conducted by the Committee revealed that there are in essence two markets for prescription drugs: a highly competitive market in which deep discounts are given to certain providers; and a relatively uncompetitive market, where the $3.5 billion dollar Medicaid program pays top dollar for drug products without any discounts provided in return for this high volume. In essence, the drug manufacturers have been denying Medicaid the same discounts it gives to other high-volume users of prescription drug products.

Just when we thought the industry had used every possible trick up its sleeve to maximize its already outrageous profits, along comes Sandoz with an unprecedented scheme that ties distribution of an antipsychotic drug to a closed patient monitoring system which is available from one and only one home health care agency- Caremark. Sandoz calls it CPMS -- the Clozaril Patient Monitoring System; I call it the Corporate Profit Maximization Scheme.

Sandoz is charging approximately $9,000 per patient in this country for the product and the associated services, a mind-boggling expense which will be borne primarily by our state Medicaid programs. That is because over 90 percent of medical services for schizophrenic patients is paid for by our tax-payer funded Medicaid programs, which are already staggering under the weight of 88 percent prescription drug price inflation in the decade of the 1980's.

What makes this price even more outrageous is the fact that the "patient monitoring services" required for the safe use of the drug -- a simple white blood cell count -- can be provided by most health care institutions, such as hospitals and health maintenance organizations, and laboratories at a minute fraction of the cost that Sandoz is charging. In addition, CPMS circumvents the time-tested system we have in this country for physicians prescribing, and pharmacists dispensing, drug products to patients. It is an insult to these health professionals that some outside home health care agency can claim to know how to treat a patient better than one's own personal health professionals.

Because the company has repeatedly refused to give us a breakdown of the costs of this scheme, we can only conclude that most of the price is pure profit for the company -- profit being paid for by you and me -- the average taxpayer -- through the Medicaid program. Because the state Medicaid programs cannot -- and SHOULD NOT -- fill the already-overflowing coffers of these companies, patients who may benefit from this drug are simply not getting it.

In my own state of Arkansas, an official of the state mental hospital in Little Rock wrote to say that the monitoring system's costs are just simply too much for the state to afford, and that patients are being denied access to a product which may prove to be very beneficial. I was shocked to learn that this hospital's total budget for prescription drugs -- which treats 850 patients annually, both inpatient and outpatient -- would only be able to treat 22 patients on Clozaril at this outrageous price. I cannot and will not stand by and let these companies perpetrate this crime on my constituents.

To provide relief to the states, and improve patient access to Clozaril and other desperately needed medication, I recently introduced S. 2605, the Pharmaceutical Access and Prudent Purchasing Act of 1990. This legislation is my attempt at developing a business-like approach to controlling the cost of prescription drugs in the Medicaid program. In short, the bill would force unwilling drug manufacturers to negotiate over the prices for prescription drug products.

Section (3) Paragraph (i) of S. 2605 was developed to address the unusual Clozaril issue. This section should make Sandoz, Caremark, Caremark's parent company Baxter, and its other partner, Hoffman-LaRoche Laboratories, see the error of its ways, and bring them to the bargaining table to force them to relieve us of their extraordinarily creative but morally bankrupt profiting scheme.

Specifically, Section (3) requires the Secretary of the Department of Health and Human Services to enter into negotiations with those drug manufacturers that will only sell their drug product to parties that also purchase certain associated "patient care" monitoring services. The purpose of these negotiations would be to determine circumstances in which health care institutions receiving Medicaid funds will be exempted from paying for such "patient care" services when they can be provided by the institution or other laboratories. The Secretary of HHS is also required to determine whether the Secretary of the Department of Veterans Affairs wants to participate in these negotiations.

Just recently, the DVA took the initiative to develop a system that can effectively monitor Clozaril therapy. Sandoz has told the DVA that their system would be as good as CPMS, but continues to force DVA to buy the drug and monitoring services from Caremark. To my knowledge, Sandoz has given no reasonable and rationale explanation for this continuing unacceptable situation.

Mr. Chairman, the Secretary of HHS currently has the capability to enter into negotiations for these purposes, but, to my knowledge, has not yet done so. I encourage him to do so expeditiously.

If the Secretary's negotiations with the manufacturer are unsuccessful for whatever reason, the Secretary can enter into a contract with another manufacturer to produce the drug for ultimate distribution to patients through a patient monitoring system approved by the Secretary. Although Clozaril is a patented product, the ability for the government to manufacture a patented product without the permission of the patent holder is well-established in law when there is some compelling national interest at stake. The government does this by exercising its power of "eminent domain", by licensing the product from the patent holder.

The patent holder(s) may recover reasonable compensation for the use of the patent by the government. This authority has been used many times in recent years by the government to produce products far less important than drugs.

Under my provision, a manufacturer awarded the Secretary's contract to produce the drug will be allowed to apply for expedited Food and Drug Administration (FDA) approval via the Abbreviated New Drug Application (ANDA) process. I strongly encourage the FDA to do everything it can to see that any ANDA for Clozaril, or other drugs for which the Secretary uses this authority, be processed through the system as quickly, but as thoroughly, as possible.

The final part of this provision requires that patient care standards be upheld whether the Secretary is successful at negotiating a means by which an institution may provide patient monitoring services in lieu of the manufacturers or if the Secretary contracts with another manufacturer to produce the drug for distribution by others. Let me say at this point that I do not question the need for patient monitoring with Clozaril, nor am I passing judgment on the ability of Caremark to safely monitor patients through its system. What I do object to is our government having to pay for a system which is markedly overpriced, outside the normal channels of patient care, and monopolistic in nature.

This provision in PAPPA should also encourage other drug manufacturers who are considering similar arrangements to consider other than sole distributors as a way of providing their product. Mr. Chairman, I have received many letters and calls from psychiatric hospitals, state mental health directors, and health professionals from my own state of Arkansas who are pleading for help in providing some sort of relief from this tremendously expensive and unnecessarily bundled scheme for Clozaril.

We must keep the pressure on Sandoz and other drug companies to recognize that we will not be willing partners in their schemes whose bottom line is to rob the American tax-payer. I am eager to hear about the proceedings of this hearing and look forward to working with the Chairman of this committee and its members in reaching an equitable solution to this pressing financial and patient care problem.

In closing, I would like to publicly urge the manufacturers involved in the Clozaril issue to move quickly to offer solutions that make them part of a realistic and fair answer rather than continue to be a major part of the problem. With or without them, however, we will address this issue if I have anything so say about it.

Thank you, Mr. Chairman, for giving me the opportunity to outline my concerns with regard to Clozaril. I look forward to working with you and your distinguished colleagues on the Committee on this and other important issues.

Judith Rebecca Hass
12615 Janelle Drive
Little Rock, Arkansas
72212

June 26, 1990

The Honorable David Pryor
267 Russell Senate Office Building
Washington, D.C. 20510

Dear Senator Pryor:

Subject: Clozaril Patient Management System

My name is Becky Hass and I am the Director of Pharmacy Services for the Arkansas State Hospital. I manage both the in-patient pharmacy in the hospital and the out-patient pharmacy, which is located in the Greater Little Rock Mental Health Center. My husband, also a health care provider, is chief resident of the Anesthesiology Department at University Hospital. I am active in various professional organizations and currently serve on the Board of Directors for the Arkansas Association of Hospital Pharmacists. I am concerned about the decision by Sandoz Pharmaceuticals to bind the drug clozapine into a monopolistic and unnecessary system of control.

The Clozaril Patient Management System (CPMS) by-passes existing and traditional avenues of health care procurement and the checks and balances inherent in our existing system. This is the scenario: A drug company develops a drug which promises to fill a niche in our current drug armamentarium. There is a problem, however, because this drug can cause a potentially fatal condition in 1-2% of the patient population. This condition can, however, be averted by recognition of its potential and exercising of the proper duty of care for the patient. Now Senator Pryor, please understand that this situation is commonplace in today's health care environment. Our current drug arsenal is full of agents which are accompanied by a host of possible ill effects from the uncomfortable to the life-threatening. A category which leaps into my mind is the cancer chemotherapeutic agents. You may also check the profiles of carbamazepine and phenelzine, two agents used in the mental health environment on a long term basis. Even potassium chloride, a simple chemical which is naturally occurring in the body, can cause cardiac arrest and death if the proper duty of care is not exercised with its administration. As with clozapine, potassium chloride requires monitoring of blood levels in both the acute and chronic situations. The delicate risk versus benefit equation is an inescapable fact of life in medicine today and the situation is capably handled on a patient-by-patient basis through the system of highly-trained, dedicated health care professionals.

If Sandoz cannot trust the doctors, nurses, pharmacists and all the other health care professionals currently in practice in this country

to properly monitor clozapine, and if Sandoz really needs a system like CPMS, practically all agents on the market today need the same restrictions. We can do away with the health care team as we know it and empower the drug companies to become the sole guardians of the patient's best interests as the CEO's sit at corporate headquarters and dictate the procedures and assign the fees they deem appropriate. These companies will need to operate stables of pharmacists and lab technicians who are paid not to think but to produce. This new system will change the medical profession from a group of highly-trained and dedicated men and women to technicians who can no longer individualize current medical practice on a case-by-case basis but must "cookbook" any given disease scenario down a predetermined pathway irrespective of any mitigating circumstances. Eventually, we can close all those expensive colleges of medicine and pharmacy because we will no longer need the sometimes illogical and imperfect blood-infused brain and we will come to rely on computer chips which are electrically-charged and perfect in their thoughtlessness. I may wax a bit Orwellian, but my logic is sound.

This brings me to the question of who needs a thinking pharmacist anyway? The optimal benefit for the patient is obtained when the perspectives of all involved health professionals are considered and integrated into the treatment regimen. As for the question of why we need a thinking pharmacist I could soapbox on this issue until the cows come home. But I will suffice it to say that the pharmacist is the only link in the chain educated and trained to balance the pharmacological concerns with sound health economics. It is through the pharmacist that rational drug therapy and sound fiscal responsibility can be combined for the benefit of both the patient and taxpayer/insurance payer in our over-burdened health care industry. Recognition of the pharmacist's dual role can provide both rational and cost effective therapy which will be the ultimate answer to the prohibitive cost concerns we face today. Sandoz has run rough-shod over our efforts toward cost containment through pharmacy-based rational drug therapy. Their CPMS program is a step backward in our attempt to intelligently develop an efficient system of quality health care that will not drown us all in a sea of runaway cost inflation.

The CPMS developed by Sandoz limits access to the people who need it most. First, access is limited from a financial standpoint. Because Sandoz will not break out the lab costs from the drug costs (and have not satisfactorily explained their reluctance to do so), the program is not being funded by Medicaid. This limits access to people who cannot afford the medication. The Division of Mental Health Services in Arkansas appropriated over $199,800 to provide patients with clozapine from March 1990 through June 1990. That program is currently full and there is no further assistance available to my knowledge. Plans for assistance of even the current clients after June 30, 1990, have not been finalized. Second, CPMS limits access

from a physical standpoint. The patient has only one option in obtaining his medication and may not under any circumstance use the pharmacy of his choice. In a rural state like Arkansas it will be necessary for the patient to conform to the needs of the drug company in order to obtain the medications. This may necessitate frequent travel in a patient population with very limited access to means of transportation.

Is CPMS expensive? Let me put it this way: Our Pharmacy Department provides medications for both the hospital (average daily census is 200 patients) and the Greater Little Mental Health Center (I figure we serve about 650 clients in the pharmacy). If we combine these two pharmacies, then we are serving the daily psychotropic drug needs of roughly 850 patients. My budget for pharmaceuticals for FY90 was $200,000 for these 850 patients. At the current cost of clozapine, I could only provide services for 22 patients for $200,000 for one year. CPMS represents an exponential jump in drug costs at a time when cost containment is so vital. Why is CPMS so expensive? Is it really necessary? Can we not trust our current system of health care professionals to handle this agent? When I compare clozapine's profile with that of other dangerous agents we currently use on a daily basis in this country, I can conclude only that the CPMS system developed by Sandoz is of no added benefit to the patient and ultimately serves only the interests of the drug manufacturers in an attempt to bypass the current rules and regulations which we have enacted in order to slow the escalating and asphyxiating costs of health care in this country today and to provide the best health care possible to all Americans..

Senator Pryor, I appreciate your time and attention on this matter. I am truly concerned as a taxpayer and a pharmacist about the precedent which Sandoz is attempting to set. Please consider the long-term and far-reaching ramifications of such a system and do not discount the possibility of a "hidden agenda" on the part of drug manufacturers.

Sincerely,

Judith Rebecca Hass, PD

cc

CONGRESSMAN LANE EVANS TESTIMONY
BEFORE THE HOUSE VETERANS' AFFAIRS
SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE HEARING
ON MENTAL HEALTH CARE FOR VETERANS WITH
POST-TRAUMATIC STRESS DISORDER AND H.R. 3037
JUNE 28, 1990

Mr. Chairman, I certainly appreciate the opportunity to testify before this Subcommittee on Hospitals and Health Care on the issue of Post-Traumatic Stress Disorder (PTSD). I want to applaud you for holding this hearing today. I believe it is important for us to carefully examine this problem and provide veterans with the health services which they deserve.

As we have seen by the National Vietnam Veterans Readjustment Study mandated by Congress, at least one in four Vietnam veterans will have suffered from post-traumatic stress disorder (PTSD) some time in his or her life. Fifteen percent of male Vietnam theater veterans have diagnosable PTSD, which is a psychological illness that afflicts persons who are exposed to a traumatic event outside the normal human experience. Combat veterans are the largest group associated with the disorder.

As you may know, PTSD has been around for a long time under various names; battle fatigue and shell shock are labels from previous wars for the same disorder. Nightmares, traumatic flashbacks and insomnia are some of the symptoms experienced by Vietnam veterans 20 or so years after they went into battle. Family, friends and loved ones may in some way or other have to endure the effects of this disorder which impair the lives of these veterans.

PTSD leaves no visible marks on veterans, but there is no question that it is a severe injury to those who have served. Over 800,000 Vietnam veterans suffer the symptoms of PTSD, but only about 10

percent have availed themselves of services or treatment either through the Vet Center or inpatient programs. Part of the problem is the availability services. Of those veterans suffering from PTSD, a third to a quarter have never seen a mental health professional. There are only 195 Vet Centers around the country and only 16 operational PTSD inpatient units in DVA medical centers. It is high time that the Department of Veterans' Affairs (DVA) provide assistance to meet the needs of these veterans.

The DVA needs to make the treatment of PTSD one of its top priorities. That is why I have joined in sponsoring H.R. 3037 which would arrange for an expansion of the services the DVA provides to veterans suffering from PTSD. The legislation wouldexpand both inpatient and outpatient treatment and would also encourage the DVA to recruit qualified professionals to administer PTSD care.

As Chairman of the Subcommittee on Oversight and Investigations of the House Veterans' Affairs Committee, I along with Representatives Jim Jontz and Jill Long held a hearing in Huntington, Indiana. The hearing examined the benefits, services and treatment provided by DVA to Indiana veterans suffering from PTSD. At that hearing, we had the opportunity to hear first hand accounts from veterans and their families who together have been battling PTSD.

If I may, I would like to read an excerpt from testimony given at that hearing by a Mr. Gary White, a Vietnam veteran. It reads:

> "My military training and Vietnam experiences caused both mental and emotional scars. These scars have not only affected me for 20 years (and Korean vets for 37 years),

but they have also affected those that I live with (my wife and children), those who I socialize with (neighbors and friends), and those that I work with. Everyone that I come in contact with will feel some effect of my mental and/or emotional condition."

We need to assure that the countless other veterans like Mr. White receive the benefits and services to which they are entitled. Those who served their country in its time of need should not be forgotten in their time of need. We need to make treatment a national priority and make sure every veteran is served. Once again, I thank you for holding this hearing and for giving me the opportunity to testify before this Subcommittee today.

STATEMENT OF REP. JIM JONTZ AT SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE HEARING ON PTSD TREATMENT AND H.R. 3037

Mr. Chairman, I thank you again for scheduling this hearing today. I am pleased that we have the opportunity today to hear testimony on the Department of Veterans' Affairs delivery of services to veterans suffering from post-traumatic stress disorder, and on the legislation which I have introduced to expand these services.

Twenty years have passed since most of the three million men and women who served our country in Vietnam came home. But for too many of these veterans, the Vietnam War lingers on.

Known as "shellshock" in World War I and "combat fatigue" in World War II, post-traumatic stress disorder -- or PTSD -- is a psychological readjustment condition which today still affects an estimated 15 percent of our Vietnam veterans.

Like some other issues which extend from our country's Vietnam experience, PTSD hasn't been well understood. The disorder wasn't recognized by the government or the mental health community until 1980, and the Department of Veterans' Affairs has been much too slow in responding to the affected veterans.

The National Vietnam Veterans' Readjustment Study, released 18 months ago by the Research Triangle Institute under contract with the Department of Veterans' Affairs, concluded that there are a substantial number of Vietnam veterans who are not receiving the treatment which they rightfully deserve from the DVA for PTSD. In fact, of the 479,000 Vietnam veterans currently suffering from full-blown PTSD, only 10 percent received any help from the DVA for their problems in the last year of the study (1988).

The findings of the RTI study were confirmed by another study published in the March 2nd edition of the Journal of the American Medical Association. The "Twins" Study, conducted by researchers in Chicago and St. Louis, found that the prevalence of PTSD is

16.8% in twins who served in Vietnam, using a sample of over 2,000 identical twin pairs who were Vietnam-Era veterans.

The conclusion is unavoidable: Our nation has failed to live up to the commitment which it made to these veterans when it sent them into war: to provide appropriate and timely care for any condition -- physical or mental -- which was contracted as a consequence of exposure to combat.

At the suggestion and with the assistance of veterans and PTSD treatment professionals in the Fifth Congressional District of Indiana and on a national basis, I introduced H.R. 3037, the Veterans PTSD Treatment and Psychological Readjustment Act last July with 45 original cosponsors.

Let me briefly summarize the bill for you.

H.R. 3037 would expand inpatient treatment for PTSD by adding 30 additional centrally-funded inpatient PTSD units. There are currently sixteen inpatient units nationwide, not all of them centrally funded.

It would add 40 additional Vet Centers to the 195 which currently exist. Vet Centers provide readjustment counseling for all Vietnam veterans, including valuable outpatient services to veterans who suffer from PTSD.

H.R. 3037 would assist in providing PTSD treatment opportunities for veterans in rural and remote areas by establishing a stable funding base for the Department's contract PTSD care program.

To staff existing and proposed PTSD units, the bill would expand the Department's Health Professionals Scholarship Program to include mental health professionals who specialize in PTSD treatment.

H.R. 3037 would give statutory authority to the Readjustment Advisory Committee, which provides critical advice to Secretary Derwinski on the problems which Vietnam veterans still face.

The bill would create a coordinated research program for the treatment of PTSD to be conducted through the recently-established National Center on PTSD. New PTSD treatment units could certainly benefit from the experiences of similar units and the research conducted at the National Center.

Finally, H.R. 3037 would establish a pilot program for PTSD care in halfway houses. This is the suggestion of the administrator at the Marion, Indiana Medical Center who is familiar with the problems that medical centers have in providing bed space for PTSD patients, given the time-intensive nature of its treatment.

While H.R. 3037 would not expand the PTSD clinical team program, I should note that the Department has established PCTs at 44 medical centers nationwide over the past two years. It is good that the Department has taken this initiative and I believe that PCTs should be established at all 154 facilities where mental health care is provided by the DVA. However, PCTs by themselves are far from an adequate response to this problem.

During the course of the last year it has become increasingly apparent that Congressional action will be necessary if we are to expand treatment opportunities to the thousands of veterans with PTSD who aren't getting help. The DVA has done little to respond to the findings of the RTI study since it was issued 18 months ago, despite the fact that waiting lists for inpatient treatment at some DVA medical centers extend for as long as a year, and cities as big as Toledo, Ohio, and Nashville, Tennessee -- both with significant Vietnam veteran populations -- have no Vet Centers.

Since H.R. 3037 was filed last year, support for this legislation has grown.

In late February, the House Veterans' Affairs Committee recommended that the DVA medical care budget be expanded to

include $7 million more for PTSD treatment, which is the CBO cost estimate for the first year's programs in H.R. 3037. Eighteen members of the committee are included among the 116 cosponsors of H.R. 3037, and it has gained the support of the American Legion, AMVETS, the Disabled American Veterans and the VFW, as well as the Vietnam Veterans of America which was instrumental in its introduction.

Mr. Chairman, I am again thankful that through your leadership, this subcommittee is addressing this issue which is important to our nation's veterans. This testimony should enable our committee to craft an appropriate response to these problems with PTSD treatment.

I appreciate the tight budget situation facing Congress, but H.R. 3037 proposes a balanced, cost-effective approach to help resolve the PTSD problem that, much like the budget deficit, has been too often neglected over this past decade. PTSD is not a condition which is healed by time; the number of veterans with PTSD is not diminishing.

Mr. Chairman, it is my hope that this committee and the Congress will pass PTSD treatment legislation during this session. For too many veterans and their families affected by post-traumatic stress disorder, one more year of waiting may be too much of a burden to bear.

Thank you.

STATEMENT OF THE AMERICAN PHARMACEUTICAL ASSOCIATION
U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON VETERANS AFFAIRS
SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE
JUNE 28, 1990
PRESENTED BY JOHN A. GANS, PHARM.D., EXECUTIVE VICE PRESIDENT

THANK YOU MR. CHAIRMAN FOR THE OPPORTUNITY TO APPEAR BEFORE THE SUBCOMMITTEE TODAY. WE COMMEND YOU AND THE SUBCOMMITTEE FOR HOLDING THESE HEARINGS ON TWO ISSUES OF DEEP CONCERN TO THE NATION'S VETERANS -- THE RESTRICTED DISTRIBUTION SYSTEM FOR THE NEW ANTI-SCHIZOPHRENIA DRUG CLOZAPINE AND THE ISSUE OF POST TRAUMATIC STRESS SYNDROME. MY COMMENTS TODAY ARE FOCUSED ON THE CLOZAPINE ISSUE.

THE AMERICAN PHARMACEUTICAL ASSOCIATION, THE NATIONAL PROFESSIONAL SOCIETY OF PHARMACISTS, IS DEEPLY TROUBLED BY THE EVENTS SURROUNDING THE ESTABLISHMENT BY ITS MANUFACTURER OF A RESTRICTED DISTRIBUTION SYSTEM FOR THE DRUG CLOZAPINE. WE ARE FIRM IN OUR RESOLVE TO SEE THE SYSTEM DISMANTLED IN ORDER THAT PATIENTS, INCLUDING THE NATION'S VETERANS, THEIR PHARMACISTS AND PHYSICIANS, WILL BE ABLE TO BETTER UTILIZE WHAT WE WOULD CERTAINLY AGREE IS A MAJOR THERAPEUTIC ADVANCE IN THE PHARMACOLOGIC TREATMENT OF SCHIZOPHRENIA.

AT THE OUTSET, LET ME ACKNOWLEDGE THE IMPORTANT WORK THAT HAS BEEN DONE ON THIS ISSUE BY THE DEPARTMENT OF PHARMACY SERVICES WITHIN THE DEPARTMENT OF VETERANS AFFAIRS. IT HAS BEEN OUR PLEASURE AT APHA TO BE IN CLOSE COMMUNICATION WITH THE V.A. PHARMACY CENTRAL STAFF AND TO SHARE, MUTUALLY, INFORMATION AND EFFORTS TO SEEK RESOLUTION OF THIS CRITICAL PROBLEM.

APhA's position on the restricted distribution system for clozapine, known by the service-marked title of Clozaril Patient Management System (CPMS), is clear and unequivocal.' We believe that the system is clinically, scientifically and economically unjustified. We have appended to our written testimony additional materials which time does not allow me to present at this hearing. But I do encourage the subcommittee's review of this material to gain additional insight into APhA's position.

Briefly, APhA opposes restricted distribution of FDA-approved drug products because such actions preclude the full involvement of pharmacists in patient care. The current situation with clozapine/CPMS is a prime example of the problems created with such a system. Focusing on a single drug, and specifically monitoring for only one side effect of that one drug, CPMS results in pharmacy care that is fragmented across multiple pharmacy care providers, is isolated from other parts of the patient's pharmacy and medical care, and is unnecessarily expensive due to duplication of resources and procedures commonly available to patients.

Specifically, APhA opposes CPMS because:

- The system interferes with established relationships of pharmacists, patients and physicians;

- The incidence of clozapine-induced agranulocytosis is insufficiently different from, and in some cases is less than, other widely available medications which may cause

THE PROBLEM. THESE MEDICATIONS ARE CURRENTLY MANAGED EFFECTIVELY BY PHARMACISTS AND PHYSICIANS IN ALL TYPES OF PRACTICE SETTINGS IN CARRYING OUT THEIR PATIENT CARE RESPONSIBILITIES;

- OTHER PHARMACEUTICAL MANUFACTURERS OF PRODUCTS WITH SEVERE ADVERSE EFFECTS HAVE WORKED EFFECTIVELY WITH PHARMACISTS AND PHYSICIANS TO PREVENT DRUG RELATED PROBLEMS, RATHER THAN CIRCUMVENTING THEM;

- FDA DID NOT REQUIRE CPMS AS A CONDITION FOR DRUG APPROVAL;

- CPMS NEEDLESSLY INCREASES THE COSTS OF CLOZAPINE THERAPY. AT APPROXIMATELY $9000 PER PATIENT PER YEAR, CPMS RESULTS IN NEEDLESS DUPLICATION OF RESOURCES FOR MANY PATIENTS WHO ALREADY RECEIVE PHARMACY, LABORATORY AND OTHER CARE AND SERVICES WITHIN THE CURRENT SYSTEM.

AS YOU HAVE HEARD FROM V.A. PERSONNEL AND OTHERS, OUR PROFESSION HAS EXTENDED MANY OFFERS TO SANDOZ TO DEVELOP MUTUALLY AGREEABLE SOLUTIONS TO THIS DILEMMA. WE FULLY SUPPORT THE NEED FOR CAREFUL MONITORING OF CLOZAPINE TO ASSURE MAXIMAL THERAPEUTIC BENEFIT WHILE MINIMIZING RISK OF ADVERSE DRUG EFFECTS. IN FACT, THE V.A. PHARMACY SYSTEM FOR MONITORING CLOZAPINE, WHICH WAS TWICE PROPOSED TO SANDOZ -- AND TWICE REJECTED -- WOULD, IN OUR VIEW, HAVE OFFERED EQUAL IF NOT GREATER MONITORING SAFETY TO THAT OFFERED BY CPMS. WE ALSO KNOW THAT THERE ARE MANY PHARMACISTS AND PHARMACY CARE SYSTEMS CURRENTLY

WORKING WITH THE MENTAL HEALTH COMMUNITY WHICH CAN OFFER THAT SAME, OR EVEN GREATER, DEGREE OF MONITORING SAFETY.

WE THEREFORE BASE OUR OPPOSITION SQUARELY ON THE ISSUE OF SANDOZ' CIRCUMVENTION OF THE PROFESSIONAL PRACTICE CAPABILITIES OF PHARMACISTS AND PHYSICIANS IN THE MANAGEMENT OF COMPLEX AND POTENTIALLY HAZARDOUS DRUG THERAPIES. WE BELIEVE THAT THIS SETS A PRECEDENT WHICH ILL-SERVES PATIENTS, PROVIDERS AND THE HEALTH CARE SYSTEM IN GENERAL. WHILE WE STRONGLY SUPPORT THE MANY ONGOING EFFORTS TO ANALYZE THE ECONOMIC, ANTITRUST AND OTHER ISSUES ASSOCIATED WITH CPMS, IT IS THIS USURPATION OF PROFESSIONAL PRACTICE PREROGATIVES THAT TROUBLES OUR PROFESSION MOST DEEPLY.

I WOULD ALSO POINT OUT OUR SUBSTANTIAL CONCERNS REGARDING THE ROLE OF THE FOOD AND DRUG ADMINISTRATION (FDA) IN THIS MATTER. IN APPROVING THE CURRENT LABELING FOR CLOZAPINE, FDA HAS INJECTED ITSELF DIRECTLY INTO THE REGULATION OF THE PRACTICE OF PHARMACY AND MEDICINE. FDA'S DECISION TO REQUIRE WEEKLY WHITE BLOOD CELL ANALYSES, RATHER THAN RELYING ON THE CLINICAL JUDGEMENTS OF HEALTH CARE PROVIDERS, REPRESENTS A SUBSTANTIAL DEPARTURE FROM THE APPROACH HISTORICALLY TAKEN BY THE AGENCY. OFFICIALS OF APHA, FDA AND THE AMERICAN MEDICAL ASSOCIATION WILL BE MEETING NEXT MONTH TO SEEK CLARIFICATION OF THIS ISSUE AND ITS IMPACT ON THE PRACTICE OF HEALTH PROFESSIONALS.

DISCUSSIONS BETWEEN APHA AND FDA STAFFS HAVE, HOWEVER, BEEN HELPFUL IN ACHIEVING SOME CRITICAL CLARIFICATIONS OF THEIR INTENT WITH REGARD TO CLOZAPINE/CPMS. A CENTRAL POINT IS THAT FDA DID NOT REQUIRE CPMS AS A CONDITION OF DRUG APPROVAL.

ALTHOUGH IT FOUND THE PROPOSAL FOR THE RESTRICTED DISTRIBUTION AND MONITORING SYSTEM "...A SIGNIFICANT COMPONENT..." OF THE PRODUCT'S LABELING. FDA FURTHER CLARIFIED THAT IT WOULD CONSIDER DISTRIBUTION AND MONITORING SYSTEMS CONTAINING THE CRITICAL ELEMENTS OF CPMS, BUT CARRIED OUT BY OTHER ENTITIES WHICH SANDOZ MIGHT CHOOSE TO RECOGNIZE, AS BEING CONSISTENT WITH FDA LABELING REQUIREMENTS. IT IS PRECISELY THIS OUTCOME THAT APHA SEEKS TO ACHIEVE.

IN SHORT, APHA BELIEVES THAT THERE ARE MANY PHARMACISTS AND MANY PHARMACY SYSTEMS, OTHER THAN THE MONOPOLISTIC SANDOZ/CAREMARK SYSTEM, CAPABLE, WILLING AND EAGER TO PROVIDE CLOZAPINE THERAPY AND MONITORING SERVICES TO PATIENTS, MANY OF WHOM STAND TO BENEFIT GREATLY FROM AN IMPORTANT THERAPEUTIC ADVANCE. WE WILL CONTINUE OUR EFFORTS TO ACHIEVE THIS OPPORTUNITY FOR OUR PROFESSION AND OUR PATIENTS, AND SINCERELY APPRECIATE THE SUBCOMMITTEE'S EFFORTS IN BRINGING GREATER ATTENTION TO THIS ISSUE.

I WOULD BE HAPPY TO ANSWER ANY QUESTIONS YOU MIGHT HAVE.

American Pharmaceutical Association
APhA
2215 Constitution Avenue, NW
Washington, DC 20037
(202) 628-4410 FAX (202) 783-2351
The National Professional Society of Pharmacists

July 5, 1990

This letter is written on behalf of several national pharmacy associations to solicit your expression of interest and possible participation in the project described more fully below. If you are interested in pursuing this project, please advise me in writing no later than Friday, July 13. Meetings with firms expressing an interest will be held at the end of the following week.

Background: Clozapine is a drug approved by the Food and Drug Administration (FDA) in late 1989 for use in treating patients with severe schizophrenia and who have failed to respond to other therapies. The drug is marketed by Sandoz Pharmaceuticals, a subsidiary of the Swiss firm Sandoz, Ltd. under the trade name "Clozaril." Clozapine has several potentially adverse side effects. One, agranulocytosis, which inhibits the production of white blood cells, is potentially fatal. In approving the application for marketing the FDA imposed a requirement that patients on this drug be monitored for this possible side effect via weekly blood testing. The FDA has stated that this requirement was a functional one and not a mandate for a specific proprietary system; however, FDA has indicated that it would not have approved the drug unless conditioned on a mandatory weekly blood draw.

Sandoz has chosen to effectuate this FDA requirement by imposing its proprietary system, the Clozaril Patient Monitoring System (CPMS), as the exclusive means for patients to obtain the drug. Under CPMS pharmacies would not be able to access the drug in the same manner they obtain other drug products. CPMS is based upon exclusive contracts with Caremark, Inc., a subsidiary of Baxter Health Care, Inc., which will do the weekly blood draws and provide the drug to the patient. Roche Biomedical Labs, Inc., a subsidiary of Roche, will do the blood work and provide the information to Caremark. Based upon the FDA requirement, Sandoz incorporated CPMS in the official labeling of Clozapine. (Sandoz rationalized CPMS on the basis of the need to closely monitor patients for agranulocytosis and to assure consistency of the data.) Sandoz has, we believe, exclusive 5 year contracts with Caremark and Roche, which corresponds exactly to the time that the patent on Clozapine expires.

Clozapine is currently targeted for a group of patients who number about 200,000 and whom are currently largely institutionalized. Of this number only 60,000 might actually be appropriate for this specific therapy. Virtually all are on Medicaid. Since its introduction the drug has been quite controversial with Medicaid directors because of its high cost, $172.00 per week patient, and the bundling of both product and lab costs in one price. Sandoz, has refused to disclose price components, which the Medicaid program needs to properly account for the drug costs and has refused to adjust prices when state and private institutions perform some of the functions of the CPMS (such as blood draws in the case of patients served in home care programs.) In Europe the price for the drug is not bundled and is considerably less than the price here; it appears to be between $20-$30 per week. Some Medicaid programs have chosen not to pay for the drug because of the bundled price; others are considering similar action.

Some staff of national pharmacy organizations have heard rumors that the drug is now being tested for wider application in cases of severe depression and refractory pyschoses. Therefore, the implications for health care, potential markets and financial stakes for all are possibly increased significantly.

Over the past weeks Sandoz appears to be modifying its CPMS in the hospital setting to permit hospital to stock the drug as starter and emergency doses, to do its own blood draws and lab work. Data must still be sent out to Caremark in order to get the patient into the System and the cost is still the same. To date Sandoz has refused to make any accommodation to the Veterans Administration hospitals (VA) which may have as many as 2,000 patients who are candidates for the drug, and which has proposed its own monitoring system. The VA is adamantly opposed to CPMS but it may be that Sandoz is prepared to grant the VA similar consessions as those given to many hospitals.

National pharmacy associations, individually and through a coordinating body, the Joint Commission Pharmacy Practitioners have strongly objected to CPMS. In late 1989 and early 1990 JCPP and individual associations wrote to Sandoz, objecting to CPMS based upon problems with patient care associated with CPMS. Sandoz has not been receptive to those arguments. Consequently, JCPP is embarking on the preparation of a legal analysis of this situation.

ISSUES AND OBJECTIVES: The pharmacy professional wants this important drug to remain on the market, but wants it to be available without the unnecessary and duplicative encumbrances that characterize CPMS. We believe that by permitting all pharmacies the opportunity to provide the drug and assume appropriate patient care responsibilities, the public health will be enhanced. We ask your firm to address the following issues.

1. Has the FDA exceeded its authority by requiring that health care practitioners follow a specific set of procedures as a condition to using Clozapine.

2. Is the contractual Clozaril Patient Management System an illegal tying arrangement or otherwise violative of the antitrust laws?

3. Has Sandoz violated the Food Drug and Cosmetic Act by changing the FDA requirement for a "functional" system into a proprietary one in the labeling for Clozapine?

4. Has operation of the CPMS, in which its original scope has been modified in institutional settings, rendered the drug misbranded or otherwise in violation of FDA requirements?

5. Has the bundling of expenses and the conduct of Sandoz in connection with Clozapine been such that its patent rights may be terminated?

If your firm is aware of other issues that should be addressed, please advise us of them.

SCOPE OF WORK: The initial scope of work is to render a "quick turn-around" legal opinion on the issues referenced above . Although no decision has been made yet, the opinion should also address issues associated with potential for litigation of this matter including, without limitation, standing, parties, venue, time costs and expenses.

CONFLICT OF INTEREST: Please advise if you have done any work for any potential party and whether that poses any actual of potential conflict to the firm or individual lawyer who may be involved with this matter.

INITIAL RESPONSE: An initial written response in expected at my office by July 13 and should include the following: an estimate of the charges and time to render the opinion, the names and background of the principal attorneys who would be responsible for the case, and a response to the conflict of interest question.

In order to assist you in your evaluation and response, we have enclosed a set of documents for you to use as needed.

We look forward to you response.

Sincerely,

William M. Hermelin
Director of Government Affairs

Enclosures

American Pharmaceutical Association
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The National Professional Society of Pharmacists

February 7, 1990

Mr. Jacques Rejeange
Chief Executive Officer
Sandoz Pharmaceuticals Corporation
59 Route 10
East Hanover, NJ 07936

Dear Mr. Rejeange:

I am writing to reaffirm APhA's unequivocal opposition to the plan developed by your company for the distribution of clozapine (Clozaril) through the so-called "Clozaril Patient Management System" (CPMS). We remain greatly distressed by Sandoz' continuing unresponsiveness to the significant patient care and public health issues created by this inappropriately restrictive and unnecessary system for drug distribution.

After review of product information materials and discussions with clinical researchers involved in the drug's development, it is our firm conclusion that CPMS is clinically, scientifically and economically unjustifiable. The system clearly interferes with established pharmacist-patient-physician relationships. Most importantly, it cannot be demonstrated to provide greater patient safety than that provided by the traditional drug therapy management and control functions of pharmacists and physicians, working on behalf of their patients.

In effect, Sandoz has created an artificial system of drug prescribing, distribution and monitoring which supplants the societally-sanctioned roles of pharmacists and physicians by using "case managers" and phlebotomists. There is simply no rational justification for such an approach.

Sandoz' own product literature provides substantial rebuttal to the need for such a plan. In the monograph entitled "Clozapine-Associated Agranulocytosis: Occurrence and Risk Management", Tables I and II on pages 4 and 5 list approximately 90 individual drug products, in 17 different therapeutic categories, which have been associated with the occurrence of agranulocytosis. Pharmacists and physicians have ably demonstated their competence in managing the potential occurrence of aganulocytosis with these products. Why do you believe that they are incapable of performing these same functions with regard to your product? Interestingly, these tables <u>do not even list potent antineoplastic agents</u>, many of which possess even greater potential for bone marrow suppression. These agents have routinely and effectively been prescribed, dispensed and monitored by pharmacists and physicians in a variety of inpatient and outpatient settings for some time.

Additional facts undercut the rationale for such a system. In discussions we have had with researchers involved in clinical trials with the drug, the occurrence rates of drug-induced aganulocytosis after four to six months of clozapine therapy fall to levels indistinguishable from other drugs with the same adverse effect. Thus, there appears to be inadequate clinical justification for weekly analysis of white blood cell counts indefinitely for patients maintained chronically on the medication. It is also pointed out by these researchers, as it is in your own product literature, that there have been very few deaths as a result of clozapine-induced agranulocytosis since 1977, when the knowledge of the potential problem became widely known among researchers using the drug. We seriously doubt that the equivalent of CPMS has been in place since 1977 in those countries where the drug has been approved for use, or in the clinical trials programs in the United States where the drug has been under study. We submit that it has been the effective practices of pharmacists and physicians in monitoring their patients for drug-induced problems that has contributed to this improved safety profile of the drug over the past 13 years of clinical research and use.

Other pharmaceutical firms with products having substantially greater toxicity and risk profiles than clozapine have successfully addressed problems of this type through effective education and collaboration with the pharmacy and medical professions. An excellent example of such educational efforts to improve prescribing, dispensing and monitoring practices is represented by the improved use of chloramphenicol. Through effective education of health care professionals, Parke Davis was able to assure improved use of its important therapeutic agent by working with the professionals best able to manage its use. Parke Davis obviously saw no need to usurp health care professionals' patient care roles through a contrived distribution system.

A more recent example, and one that is quite instructive, involves the substantial efforts on the part of Roche Laboratories, in cooperation with the FDA and health professional organizations. These efforts have resulted in improving the quality of prescribing, dispensing and monitoring of isotretinoin (Accutane) to prevent the essentially universal occurrence of fetal abnormalitites in women who take the medication during the early stages of pregnancy. While requiring additional testing and monitoring to help avoid the use of the drug in women who are pregnant, Roche remains committed to utilizing the pharmacist and physician to assure the best possible use of its products. Few would question the severity or tragedy of isotretinoin's potential adverse effects, which clearly match or exceed those of clozapine.

Further evidence of the lack of necessity of this system is provided by information received through communications with the Food and Drug Administration. It is clear that FDA has not required the establishment of CPMS as a condition for approval of clozapine. And while this fact has been well established, we continue to hear of discussions between Sandoz representatives and various pharmacy, state health, state mental health and other professional groups in which CPMS has been justified on the basis of FDA requirements. We strenuously object to such misrepresentations.

Most recently, we have learned of an initial proposal put forth by the Department of Pharmacy Services of the Veterans Administration. This plan would have provided computerized tracking and control of clozapine dispensing through interlinking of white blood cell laboratory data and the dispensing process, in both the inpatient and outpatient settings of the VA system. We have learned further that this initial proposal has been rejected by Sandoz as an alternative to CPMS for VA patients. The level of control offered by the VA system would, in our view, meet or exceed the safety monitoring capabilities of CPMS. We can only conclude from such a decision that patient safety is not the principal goal of CPMS.

We are equally distressed by the proposed schedule of charges for clozapine therapy and the associated CPMS activities. The estimated charges of approximately $9000 per patient per year for clozapine therapy through the CPMS substantially exceed the expected costs for drug therapy and associated monitoring in the current health care system. The monopolistic mechanism by which patients and providers secure both drug and related monitoring services, including the almost universally available laboratory analysis of white blood cell counts, clearly contributes to this excess. At a time when cost-effective health care is clearly a priority in the United States, CPMS stands out as a particularly inappropriate scheme.

The nation's pharmacy organizations have extended to Sandoz many offers in recent months to cooperate in devising a program for distribution and monitoring of clozapine that takes advantage of the time-tested system of drug prescribing, dispensing and monitoring that has served patients and the health care system so well in the past. We can only conclude, in light of the substantial body of evidence refuting the need for or desirability of CPMS, that the rationale for CPMS is based on the economic advantages inherent in the system for Sandoz and its exclusive partner, Caremark. In our view such corporate irresponsibility has no place in America's health care system. We will therefore explore all appropriate avenues available to us to seek the dismantling of CPMS, and any future systems similar to it, which ill serve the nation's patients, health care professionals and the public.

Sincerely,

John A. Gans, Pharm.D.
Executive Vice President

JAG/cew

Sandoz Pharmaceuticals Corporation

SANDOZPHARMACEUTICALS

Jacques F. Rajeange
President and Chief Executive Officer
Sandoz Pharmaceuticals Corporation

Group Vice President
Sandoz Corporation

59 Route 10
East Hanover, New Jersey 07936-1951
201.503.8125

February 15th 1990

John A. Gans, Pharm.D.
Executive Vice President
American Pharmaceutical Association
2215 Constitution Avenue, N.W.
Washington, DC 20037

Dear Dr. Gans:

Needless to say, I am deeply concerned about APhA's continued opposition to the Clozaril Patient Management System (CPMS), as set forth in your letter of February 7, 1990.

At the outset, let me reassure your membership that CPMS℠ represents a unique approach to a unique situation. The extensive studies that we have conducted with Clozaril® (clozapine) over the years have convinced us beyond any doubt that CPMS is the only documented way to minimize, as far as possible, the very real risk of agranulocytosis among Clozaril® patients. It is for that purpose, and no other, that Clozaril® will be dispensed only through CPMS. We have never experienced a similar need for any other product, and it is extremely unlikely that we will require such a delivery system in the future.

We appreciate and fully support the traditional and vital function that pharmacy performs within our health care system. In that regard, we have been responsive to suggestions about CPMS from you and your colleagues. Since the initial CPMS idea was discussed with organized pharmacy, we have made important strides in enhancing the role of pharmacy within the system. In fact, CPMS now provides for the professional services of two pharmacists in most cases as an additional precaution. That expanded role is a direct result of the helpful guidance provided by APhA and others in the JCPP.

As to the FDA -- you are correct, the FDA did not require CPMS as a condition of approval of the NDA for Clozaril®. However, they fully support the concept and have indicated that the dispensing of the drug not in accordance with CPMS might constitute a violation of the Federal Food, Drug and Cosmetic Act. Accordingly, it seems that the FDA agrees that CPMS is the only effective and documented way to achieve our goal -- to protect the Clozaril® patient, as much as we possibly can.

While comparisons of Clozaril® (clozapine) with other drugs may not be necessarily relevant, your reference to chloramphenicol is particularly appropriate. The chloramphenicol disaster is exactly what we are attempting to avoid with CPMS. When that antibiotic product was introduced some forty years ago, it was over-prescribed by thousands of eager and well-meaning physicians. The results are only too well-remembered by the medical community. Indeed, the improved use of that product has now finally resulted through the effective collaboration of medicine and pharmacy. However, before that collaboration coalesced, numerous cases of agranulocytosis resulting in death occurred from the improper use of chloramphenicol -- we must do all we can to prevent that from happening with Clozaril®.

In view of our long and valued association with APhA, I was particularly distressed to hear that you consider CPMS to be an example of corporate irresponsibility. On the contrary, we feel that our effort to protect, as far as we can, the Clozaril® patient population constitutes total corporate responsibility -- it seems that others agree with us. For example, I have enclosed an article from the June 17, 1988 edition of SCRIP, a highly respected international publication which reports exclusively on the pharmaceutical industry. The focus of the article is a comparison of CPMS with the Hoffmann-LaRoche experience with Accutane®, coincidentally one of the other drugs you cite in your letter. As you will see, the author certainly considers our system to be responsible. In fact, he also considers it to be ingenious, interesting and innovative. The article also chronicles the severe problems and pressures encountered by Roche in spite of its sincere efforts to safeguard Accutane® patients.

Sandoz Pharmaceuticals has worked diligently over the years to build an open and cooperative partnership with members of organized pharmacy. That attitude has continued throughout our sometimes spirited conversations regarding Clozaril®. Once again, we recognize the important role played by pharmacy professionals, both outside and within CPMS. Your support is of great importance to us. We regret the displeasure you express over CPMS. We ask that you put aside these limited differences and support our program to address the unique needs of the Clozaril® patient.

Sincerely,

Jacques F. Rejeange

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

American Pharmaceutical Association
c/o Arthur H. Kibbe, Ph.D.
C. Edwin Webb, Pharm.D., M.P.H.
2215 Constitution Avenue, NW
Washington, D.C. 20037

MAR 14 1990

Dear Drs. Kibbe and Webb:

This letter responds to your inquiry about the meaning of the following statement in the "How Supplied" section of the approved labeling for clozapine (Clozaril):

> Clozaril is available only through the Clozaril Patient Monitoring System [CPMS], a program that combines white blood cell testing, patient monitoring, pharmacy, and drug distribution services, all linked to compliance with required safety monitoring.

Since the approval of Clozaril, there has been some confusion about the meaning of the quoted language and the extent to which FDA would consider distribution schemes other than the scheme currently proposed by Sandoz, Clozaril's manufacturer, to be consistent with the product's approved labeling. This letter sets forth FDA's interpretation of quoted language.

Clozapine, a drug indicated for the management of severely ill schizophrenic patients who fail to respond adequately to standard antipsychotic drug treatment, is associated with an unusually high cumulative incidence of agranulocytosis (1-2% at one year), a condition that can be fatal. Fortunately, and unlike many other serious adverse reactions associated with drugs, fatal outcomes associated with agranulocytosis can be reduced, perhaps even prevented, by early detection. FDA therefore deems frequent monitoring critical to the safe use of the drug. We had long been concerned that distribution of clozapine through the usual channels, even with labeling urging frequent monitoring of white blood cells counts, would not succeed in regularly providing early detection of drug-induced agranulocytosis and would result in unnecessary deaths. Without a means of assuring procedures for early detection, there was serious question about whether the benefits of clozapine, although considerable, outweighed its risks, and thus whether the drug could be approved. Early in the review of the NDA for Clozaril, however, Sandoz notified FDA of its intention to distribute Clozaril under a restricted system (the CPMS, Clozaril Patient Monitoring System) that would require weekly white blood cell testing and patient monitoring as the conditions for a patient's obtaining continued supplies of the drug. This plan appeared likely to minimize the risk of death associated with the use of Clozaril and FDA's knowledge of the basic elements of Sandoz' restricted distribution scheme played an essential role in the agency's weighing of the risks and benefits of the drug.

The approvable letter issued by FDA for Clozaril described the role of the CPMS as follows:

> We acknowledge your intention to market and distribute Clozaril only under the CPMS. Please be aware that the approvability of Clozaril is not conditioned upon your agreement to limit the distribution of Clozaril in this manner. Nevertheless, please also be aware that the proposed draft labeling for Clozaril specifies in several places that Clozaril would be available only under this restricted distribution system. Consequently, Clozaril could be considered misbranded if it were to be made available outside of the CPMS.

Thus, although distribution through the CPMS was not a condition of Clozaril's approval, FDA considered the statement in the "How Supplied" section concerning the CPMS not merely descriptive of Sandoz's plans for supplying the drug, but a significant component of the drug's labeling. In reaching its determination that Clozaril could be safely and effectively administered "as labeled," FDA relied on the statement in the label that Sandoz planned to distribute the drug only under the CPMS. But the specific details of Sandoz's planned distribution scheme (e.g., a specific, named contract vendor) were not known to FDA at the time of approval and were not considered in our review of the application. The only aspect of the system that was considered essential to the safe and effective use of Clozaril was a distribution scheme that conditioned drug dispensing on weekly white blood cell counts and patient monitoring. FDA's approval of labeling that the drug be supplied through the "Clozaril Patient Monitoring System" refers only to this essential aspect of the system, not to the specific commercial details developed by Sandoz to implement the system.

Thus, FDA interprets the reference to the Clozaril Patient Monitoring System in the drug's labeling as a reference to any scheme that Sandoz chooses to utilize that establishes weekly white blood cell testing and patient monitoring as the prerequisites for dispensing continued supplies of the drug to the patient. FDA does not regard the reference to the CPMS as recommending that any particular entity carry out any of the contemplated tasks, so long as the crucial elements of the scheme are assured. Although Sandoz may have chosen a specific vendor to implement the CPMS, FDA considers it compatible with the current labeling for Sandoz to agree to provide Clozaril through any other entities, public or private, that have made specific arrangements to assure that each patient receives weekly white blood cell monitoring as a precondition for dispensing the drug to that patient. What we would not find compatible with the current labeling is distribution through community pharmacies and reliance on voluntary compliance by physicians with the recommended testing and monitoring. Sandoz would, of course, remain responsible for assuring that any system through which it distributed Clozaril assured that drug dispensing was conditioned upon weekly testing and monitoring. As described in the approvable letter, a distribution scheme that did not provide this assurance could result in a violation of the Federal Food, Drug, and Cosmetic Act.

FDA emphasizes that its decision to approve labeling for Clozaril recommending that dispensing of the drug be conditioned on special testing and monitoring represents an extremely unusual case. The combination of (1) a high incidence of a potentially fatal adverse reaction, (2) the inability to identify in advance patients who will suffer the reaction, (3) the probability that the risk of death can be substantially reduced by weekly testing and monitoring, (4) FDA's experience that physicians do not always comply with label recommendations for relatively burdensome testing and monitoring, and (5) an unusual patient population that cannot be relied on to take responsibility for regular testing, together caused FDA to approve labeling that included a plan that conditioned distribution on the assurance of patient testing and monitoring. FDA expects that few other drugs will present a combination of circumstances justifying such a recommendation. FDA would not permit such a recommendation to appear in a drug's labeling simply because the drug's manufacturer wished, for its own reasons, to limit distribution of the drug.

Sincerely yours,

Carl C. Peck, M.D.
Director
Center for Drug Evaluation and Research

American Psychiatric Association

1400 K Street, N.W., Washington, D.C. 20005 • Telephone: (202) 682-6000

TESTIMONY

OF THE

AMERICAN PSYCHIATRIC ASSOCIATION

BEFORE THE

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON VETERANS' AFFAIRS
SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE

ON

THE DELIVERY OF MENTAL HEALTH CARE SERVICES

IN THE

DEPARTMENT OF VETERANS' AFFAIRS

PRESENTED BY

WILLIAM H. REID, M.D., M.P.H.
MEDICAL DIRECTOR
TEXAS DEPARTMENT OF MENTAL HEALTH AND MENTAL RETARDATION

ON

JUNE 28, 1990

Mr. Chairman and Members of the Subcommittee, I am William H. Reid, M.D., M.P.H. I am Medical Director for the Texas Department of Mental Health and Mental Retardation and Professor and Liaison for MHMR Affairs for for the University of Texas System. I appear before you today on behalf of the American Psychiatric Association, a medical specialty society representing over 36,000 psychiatrists nationwide. Our comments today will focus on the delivery of mental health care services in the Department of Veterans Affairs (DVA); the DVA's ability to care for veterans suffering from post-traumatic stress disorder (PTSD); and the impact on the delivery of DVA mental health services from the purchase and prescription of Clozaril.

Let me begin with the highlights about Clozaril, the trade name for an atypical antipsychotic medication know as clozapine, recently approved by the Food and Drug Administration (FDA). Although this drug represents a breakthrough in successful treatment of chronic schizophrenia patients, it has at the same time caused concern among state policymakers, physicians and other health care administrators. These concerns are based on 1)its high cost, which effectively limits access to the drug for a great many disabled patients (including DVA patients), and 2)its distributors' interference with the historic physician/patient relationship.

My testimony will return to the Clozaril issue, but first let me share with you how the DVA's psychiatric patient workload over the last five years has significantly increased. Since the implementation of the Resource Allocation Methodology (RAM) (the equivalent of hospital Diagnosis Related Groupings (DRGs) which did <u>not</u> apply to psychiatric hospitals or psychiatric units of general hospitals because the research data did <u>not</u> support DRGs) DVA psychiatry has experienced a 21% increase in episodes of care and a 13% increase in the number of unique individuals treated. In 1984, the percentage of discharges for individuals suffering dual diagnosis conditions involving a serious psychiatric disorder and an alcohol or substance abuse disorder was 48.5%. This figure rose to 89% in 1988. Yet, despite the increased census and an evidenced need for more complex treatment with a higher level of care, the proportion of DVA funds distributed to psychiatry

bed sections has declined. From 1984 to 1987, the overall inpatient direct care dollars distributed to psychiatry decreased 5.7%, as contrasted to medicine and surgery whose funding increased 2.6% and 7.1% respectively.

The RAM model provides incentives for markedly shortening the length of stay and for developing outpatient treatment and alternative delivery settings. Although psychiatry supports the concept that more patients should, when appropriate, be treated in an alternative setting, one must recognize that there are still large numbers of patients who because of the nature of their illnesses, must receive inpatient treatment. DVA psychiatry has responded to the demands of the RAM model with a 34.6% decrease in length of stay between 1984 and 1987. However, during that time, there has been a 20% decrease in dollars spent per "episode of care." Since there has never been an increase in funding, the effect of RAM implementation upon delivery of psychiatry services in the DVA has been to increase outpatient care at the expense of ignoring the increasing inpatient workload.

One might assume that the decrease in psychiatric inpatient care resources is related to a corresponding increase in outpatient care for psychiatric patients. This is not the case. Only 27% of the lost inpatient psychiatric full-time employee equivalents (FTEEs) can be attributed to a gain in outpatient FTEEs. Where do the "savings" from psychiatric inpatient care go? From 1984 to 1987, psychiatric outpatient direct care dollars increased 35.6%. Outpatient direct care dollars increased 54% for surgery and 11% for medicine. The DVA's ability to address the needs of <u>all</u> psychiatric patients is being severely hampered by an inadequate distribution system.

In addition, the DVA now confronts the added cost of providing Clozaril. While there are currently 80 patients in DVA facilities receiving this medication (which costs $9,000 per patient annually) on a "compassionate use" program, there is no indication "compassionate use" is a lifetime commitment for even this patient population. New patients needing the medication — and there are a great many — are not eligible for any such funds. DVA medical centers may be forced to

choose between spending funds they do not have and providing clinically proved successful treatment to their most severely ill psychiatric patients.

Schizophrenia is a severe, chronic, lifelong illness which strikes more than two million Americans over the course of their lifetimes. Approximately 40% of all hospitalized psychiatric patients in the United States suffer from this most disabling form of mental disorders. In the VA alone, there were more than 71,000 inpatient admissions in FY 1988 for patients diagnosed with schizophrenia. The use of antipsychotic drugs in short-term and maintenance treatment of schizophrenia has been well established over the past 30 years. However, at least 10% to 20% of patients derive little benefit from the current typical neuroleptic drug therapy. These individuals require more intensive medical and psychosocial care, and are subject to the persistent disabilities associated with chronic schizophrenia. Over the past decade, considerable effort has gone into the development and testing of potential antipsychotic compounds designated "atypical."

As noted at the beginning of my testimony, Clozaril is the brand name for an atypical antipsychotic medication, clozapine. The drug, first introduced in Europe in the late 1960's, appears to have significant antipsychotic potential, helping chronically psychotic patients whose illnesses are resistant to conventional antipsychotic (or "neuroleptic") medications. The drug is highly effective for most schizophrenic patients, and — most important for our purposes here today — has been proven to offer good to excellent results for approximately 30% of schizophrenic patients who do not respond to other medication. In addition, use of the drug does not produce some of the side-effects and adverse effects — some quite significant — of other antipsychotic medications, (such as symptoms similar to Parkinson's disease: rigidity, tremor, slowed movement, and muscle spasms). Patients taking Clozaril also do not suffer from the severe and sometimes crippling adverse effect sometimes seen with most other antipsychotic drugs, tardive-dyskinesia.

In the early years of it's European use, however, Clozaril was associated with a number of deaths related to a bone marrow disorder called agranulocytosis. Careful studies during the 1970's and early 1980's taught us much about predicting and preventing this dangerous condition.

Sandoz Pharmaceutical Corporation introduced Clozaril into the United States market in February, 1990. It's introduction was made possible in part by the low cumulative incidence of agranulocytosis found when patients are properly monitored; 1-2% after a year of treatment. The FDA concurred that Clozaril should be made available to certain schizophrenic patients so long as appropriate monitoring can be carried out. Sandoz itself mandated that monitoring take place through a proprietary mechanism called the Clozaril Patient Monitoring System (CPMS). The restrictive distribution system includes an exclusive contractual agreement between the manufacturer (Sandoz), a national home health care company (Caremark) and a national laboratory (Roche Laboratories). Their system provides for weekly supplies of Clozaril in conjunction with a weekly blood sample collection which is sent to Roche Laboratories for a simple white blood cell count (WBC). Caremark employees draw the blood and serve as rudimentary case managers. Roche performs the WBC and reports the results to the case manager. The CPMS also maintains nationwide data with regard to each patient in the system.

There are several problems associated with the current distribution of Clozaril. The most obvious is cost. Sandoz is charging $172 per week per patient, $9,000 per year, for the drug and CPMS. These charges are in addition to physician, nursing, and other clinic costs associated with the patient's care. For comparison, the prescribing and monitoring costs of other neuroleptic medications are generally about ten times lower, rarely exceeding $1,000 per year per patient. Clozaril should be effective in the treatment of 30,000 to 60,000 of patients who do not respond to other drugs. A large portion of the cost for this new drug and CPMS will fall to Medicaid and to the VA.

In the approval letter issued by FDA for Clozaril, the role of the CPMS was described as follows:

> We acknowlege your intention to market and distribute Clozaril only under the CPMS. Please be aware that the approvability of Clozaril is not conditioned upon your agreement to limit the distribution of Clozaril in this manner. Nevertheless, please also be aware that the proposed draft labeling for Clozaril specifies in several places that Clozaril would be available only under this restricted distribution system. Consequently, Clozaril could be considered misbranded if it were to be made available outside of the CPMS.

Clearly, Sandoz is not limited to utilizing Caremark as the sole provider of the CPMS. According to the FDA, the requirement for a CPMS "refers only to this essential aspect of the system, not to the specific commercial details developed by Sandoz to implement the system." Yet, to our great surprise, when the Department of Veteran Affairs tried to gain company approval for its own Clozaril monitoring system, it was flatly rejected. A DVA national task force had developed the plan, after it was estimated that costs for the drug alone would be about $18 million a year under CPMS since the DVA treats about 2,000 chronic schizophrenic patients. VA medical facilities do have the skilled medical personnel to monitor this medication and a nationwide medical data bank which can follow each patient and protect his or her confidentiality. What they do not have are the resources to pay for Clozaril if bound to its current sole source protocol.

This Subcommittee should also know that Sandoz has refused to provide states and other public funding sources with a breakdown of the various costs and charges attached to the drug and the components of the CPMS. Such information would help justify their charge for Clozaril and help convince, for example, Medicaid officials to support some or all of those costs. Instead, Sandoz simply reiterates the findings of a private research corporation retained by Sandoz itself, which state that 80% of those receiving the drug while outpatients (that is 80% of the 30% that respond positively to the drug) require no rehospitalization over a two year period, and that public savings related to hospitalization costs should more than make up for the cost of the drug and the CPMS. It is true that the level of improvement in some patients taking Clozaril is truly dramatic. Of 1700 patients

taking Clozaril in United States research protocols, 72%-82% have required no rehospitalization in more than two years and the remainder usually required only short hospitalizations. However, what Sandoz has not calculated is the expense of rehabilitating patients into society and providing the required continuum of medical and social care for those who have been outside the mainstream of society — in hospitals or board-and-care homes, for example — for so long. Nor does their position address the greatly lowered savings for public health care system (such as the VA), who, because of the rising cost of medical care, often do not have the initial resources needed to provide medical and psychiatric services to those who deserve them. Sandoz has effectively denied access to that which, for many, is the only avenue of hope.

Further, the FDA has disenfranchised physicians from their historic, customary, appropriate, ethical and legal patient care responsibilities by establishing a labeling requirement for Clozaril which interferes with physician patient prescribing practices. You have heard us state in previous testimony that the importance of providing fully-staffed, well-trained psychiatric units in VAMCs across the country cannot be overemphasized. The development of Clozaril is an example of how scientific advances have served to increase the relationship between physical and mental health, increasing the danger in misdiagnosis. Psychiatrists, as physicians, have the training and competence to provide a medical differential diagnosis and treatment plan. Psychiatric patients in VA facilities suffer a high incidence of co-morbidity. A proper understanding of the diagnostic and treatment considerations that affect them is essential.

Will Caremark's nonphysician employees, trained to take blood samples and serve as rudimentary case managers, be qualified to detect or monitor Clozaril's other serious side effects? Side effects which include seizures, marked sedation, tachycardia, hypotension, hyperthermia, nausea, weight gain, and elevation of liver enzymes suggesting a possible acute hepatic inflammation? Are these employees trained to recognize the severe withdrawal symptoms which can occur if dose reductions are not carefully carried out? Many patients must

take one or more medications in addition to Clozaril, for psychiatric or other medical conditions. Although we know of no drugs that produce catastrophic interactions with Clozaril, our knowledge and experience with drug combinations is still limited. The prescribing physician, with his or her familiar medical team, is the most appropriate individual to monitor and manage the patient's medication, and overall clinical care.

Also, while psychiatrists, pharmacists, state mental health officials, and advocates for the mentally ill have raised a chorus of disapproval over the unprecedented monitoring requirement — from loss of professional autonomy to costs which limit access to the medically indigent severely mentally ill — it exploded into stormy debate at our May annual meeting. As a representative of the Friends and Advocates of the Mentally Ill (FAMI) said, "It's the first drug ever that you can't get through a doctor, you can't get through a hospital, you can't get through a pharmacy. Where will this lead?"

APA is also concerned about Sandoz's nationwide Clozaril/CPMS data bank. We are strong proponents of patient rights to privacy and confidentiality. We are not at all sure what kinds of data are being solicited by Sandoz, what various uses Sandoz may have for those data, or who will have access to the information. We strongly urge that strict guidelines currently in place for other medical records be required for the use and operation of Sandoz's nationwide system.

You have also asked that we comment on the DVA's ability to care for veterans suffering from Post-traumatic stress disorder (PTSD) and H.R. 3037, legislation providing for the expansion of PTSD services. The need for expanded services is clearly illustrated in the results of the National Vietnam Veterans' Readjustment Study (NVVRS), which found that 15.2% (480,000) of all male Vietnam theater veterans currently have PTSD. Despite this, the NVVRS data show that approximately 90% of the 480,000 veterans with current PTSD have never used VA mental health resources. These findings support the contention of many practitioners in the field that there is a substantial unmet need of veterans suffering from PTSD.

As the Special Committee and others have looked at the utilization of care among this veterans population, several facts stand out. Among those veterans seen at both VAMCs and vet centers, 42.9% were hospitalized at least once. In addition, average level of adaptive functioning — an indication of the severity of the illness — is more impaired among veterans with PTSD co-diagnosis. These two finding strongly suggest, and perhaps confirm, of the severity of this illness. These hospitalization rates are an indication that veterans suffering from PTSD have substantial need for a full array of mental health services.

We also know that PTSD is frequently a chronic disorder. About one-half of male theater veterans and one-third of female theater veterans, who ever had PTSD, still have it today. Corrective treatment will require ongoing contacts with the VA or other mental health facilities. This has substantial implications for funding, in that we must recognize that our commitment to these veterans will be continuous and that their condition cannot be completely treated by one episode of care. Veterans diagnosed as suffering from PTSD, are also very likely to also be suffering from at least one other psychiatric disorder. The most common co-existing diagnosis observed is alcoholism. Twenty-two percent of all Vietnam theater veterans with PTSD report current alcohol dependence problems. Treatment programs must be organized to utilize this information and to direct resources in an effective manner.

The NVVRS showed that 61.7% of veterans with PTSD had received mental health care from some source; one-third had received their care from the DVA. Half of those with PTSD currently receiving care are using DVA mental health services. Approximately 20% of veterans with PTSD have used DVA mental health facilities, at some time upon leaving the military, and one-half of those received services within the twelve months prior to study. In contrast, when all veterans — not just those with PTSD — are considered, we find that only about 10% have ever used the DVA for <u>any</u> purpose. This means that veterans recognize the DVA as a major source of care for PTSD, if not the main source. We must encourage and expand the DVA's expertise and its services in this area.

- It is essential that the existing DVA PTSD clinical teams be further supported. Current funding permits the existence of only 23 clinical teams around the nation. There is clearly a need for many more, as there is a need for standardization of our inpatient treatment design. We should examine inpatient bed allocation and dedication of resources by region. It is essential that standards for treatment and staffing models be established for these special units. With 23 newly selected treatment teams and sixteen specialized treatment units for PTSD and the National Center on PTSD, there are approximately 45 identified sites providing dedicated PTSD services.

Research and treatment of PTSD needs to be adequately funded to address the strong needs indicated by the results of the NVVRS study. H.R. 3037 would authorize expansion of PTSD services. However, much of the new monies would be used to expand the vet center programs, of which there are already 195. In addition, $10 million of the authorization would be allocated for contacts with private facilities and therapists for the treatment of PTSD. The vet center program plays a critical role in the treatment of PTSD and any expansion of current services should be coordinated through the existing VA health care delivery system if the necessary continuum of care is to be provided. However, we feel that this money would be more efficiently spent through further expansion of DVA PTSD treatment teams and inpatient PTSD units. These specially-trained work teams are proven and effective, and should serve as the national model for treatment of PTSD. In our testimony before the House Appropriations Subcommittee on VA-HUD-Independent Agencies we requested increased funding of $12.4

- million be distributed for 25 new PTSD clinical treatment teams; three new inpatient PTSD units; the National Center on PTSD for treatment, education and research activities; and augmentation of existing inpatient PTSD units to decrease waiting lists.

Mr. Chairman, we greatly appreciate your effort, and that of the Subcommittee's to address the critical health care needs of mentally ill veterans. As we have indicated, the DVA is struggling to meet the current needs of veterans suffering from mental illnesses like PTSD and schizophrenia. New resources must be allocated and old resources

reallocated if patients are to receive the quality to which they are entitled.

Thank you for this opportunity to testify. I would be happy to answer any questions you might have.

American Psychological Association
Advancing psychology as a science, a profession, and as a means of promoting human welfare

Testimony of
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on behalf of

THE AMERICAN PSYCHOLOGICAL ASSOCIATION

AND

THE ASSOCIATION OF VA CHIEF PSYCHOLOGISTS

before the

HOUSE COMMITTEE ON VETERANS' AFFAIRS,
SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE

June 28, 1990

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Good Morning. Mr. Chairman, I am Kenneth A. Klauck, Chief of Psychology Service at the Clement J. Zablocki VA Medical Center in Milwaukee, WI. I am testifying, today, on behalf of the 100,000 members of the American Psychological Association (APA) and the Association of VA Chief Psychologists (AVACP), of which I am the immediate past president. I have had over 25 years of experience with the VA mental health care system and have also served as the President of the APA Division of Psychology in Public Service.

APA is the major scientific and professional association representing psychology in the United States. Many of our members are researchers and practitioners in the Department of Veterans Affairs' (DVA) outpatient clinics and medical centers across the country. Within the Veterans Health Service and Research Administration there are 1587 psychologists who are trained as practitioners/scientists and employed full-time. In addition, 175 psychologists work part-time. The Association of VA Chief Psychologists represents 130 Chiefs and 50 Assistant Chiefs of Psychology Service with the Veterans Health Service and Research Administration.

Mr. Chairman, members of the Subcommittee, on behalf of the APA and the Association of VA Chief Psychologists, I wish to thank you for giving me the opportunity to testify today regarding pressing issues facing our Nation's veterans and weighing upon the DVA mental health care system. DVA psychologists indeed have first hand experience in both shaping a system for delivery of effective, quality mental health care services to Veterans as well as first hand experience with the frustrations caused by shortcomings in DVA mental health care.

Because you have asked that we comment both on mental health care generally, as well as the treatment of veterans suffering from Post Traumatic Stress Disorder (PTSD), I will first make a few comments regarding the need for increased attention to the mental health needs of our Nation's Veterans and will mention some notable programs within the VA which directly and indirectly address these needs.

VA MENTAL HEALTH CARE

The Association of VA Chief Psychologists and the APA are committed to providing comprehensive, effective mental health services to Veterans. I am proud to serve as a VA Chief Psychologist. I also believe that the VA model for delivery of mental health services to our Nation's veterans is exemplary given the tremendous demand for mental health care. As documented in the 1985 Keaty Report, approximately 40% of all VA beds are occupied by veterans who suffer from psychological disorders and yet less than 10% of the VA's research resources are targeted for mental disorders. While mental health professionals are desperately attempting to meet the needs of the veterans they care for, it seems clear that more resources need to be allocated for research and treatment of psychological disorders.

As has been reported, there is a high incidence of alcohol and drug abuse, Post Traumatic Stress Disorder (PTSD), anxiety and depression associated with the Veteran population. While the Veterans Health Service and Research Administration (VHS & RA) has developed a rational and effective model for addressing the mental health needs of veterans, more must be done to improve the scope of our services.

For examole, last year I testified before the Senate Committee on Veterans' Affairs in favor of the development of Mental Illness Research, Education and Clinical Centers (MIRECC) which, under S.13, would have been established in up to five DVA health care facilities. These training and research programs would allow for the coordination of research, the training of health care personnel, and the development of improved models of clinical services for eligible veterans. The model for MIRECCs has proven effective in the field of gerontology. The Geriatric Research, Education and Clinical Centers (GRECCs) have been extremely effective, primarily because of their multidisciplinary approach to program administration, funding, research and implementation. Partnerships with graduate schools of psychology, medical schools, nursing, social work, and other mental health disciplines would increase DVA mental health care personnel exposure to advancements in the provision of quality mental health care services. Such a program would also assist the VA in recruiting and retaining much needed mental heath care

professionals including qualified psychologists whose training and expertise are critical to the provision of quality mental health care services. There is evidence that the DVA system is not providing adequate incentives to members of our profession and is finding it difficult to recruit and particularly to retain well-trained, highly experienced psychologists. The MIRECC programs would add professional opportunities to the VA program to help remedy the recruitment and retention dilemma.

The APA and the AVACP also support the expansion of the VA Homeless and Chronic Mentally Ill program (VA HCMI). This program, implemented in 1987, has served thousands of homeless veterans through a program of community outreach, health care services and residential treatment. The VA HCMI program responds to a significant need. According to studies on the homeless, between 18% and 51% of the total homeless population is made up of veterans, many of whom served in Vietnam. Assessments of individuals for psychological and medical problems, outpatient treatment, residential treatment outside the DVA and case management are being accomplished with the assistance of dedicated outreach workers. The HCMI program's track record has been excellent and we support efforts to extend the program and remove its designation as a pilot project.

Finally, I wish to mention one other DVA program which I believe holds great potential for aiding our efforts to care for Veterans suffering from mental disorders. The Compensated Work Therapy (CWT) program provides numerous therapeutic benefits to veterans relating to job skills and training. Psychologists in the VA have a long history of providing comprehensive vocational rehabilitation assessment and program support within VA medical centers in cooperation with our veterans benefits colleagues and rehabilitation services. CWT is a valuable tool in treating mentally ill and substance abusing Veterans and we continue our support for expanded CWT programs . In addition, we are supportive of proposals to link the CWT program with therapeutic housing. A therapeutic residence program can be a critical link in the transition of the mentally ill and substance abuser from inpatient care to independent living.

Mr. Chairman, it is becoming quite clear that the most cost-efficient and effective way of treating all persons with mental disorders is to tailor services to individual need. To do so requires access to a range of options for providing a continuum of mental health care. For many veterans, inpatient care alone is insufficient or inappropriate. Often individuals desperately need less intensive aftercare to ensure continued recovery and adjustment. I believe the programs that I have mentioned, some of which are currently in operation, represent the DVA's recognition of the wisdom in providing a continuum of mental health care services to veterans.

MENTAL HEALTH CARE TREATMENT OF PTSD

The same concept of providing a continuum of mental health care services is especially important in the treatment of veterans suffering from Post Traumatic Stress Disorder (PTSD). Clearly the DVA has a particular responsibility for the care of veterans with PTSD. I am sure I need not reiterate the statistics regarding the number of our veterans suffering from this serious psychological disorder. It bears repeating, however, that studies confirm that the mental health needs of 829,000 Vietnam theater veterans, are not being fully met. Psychologicai interventions have been effective in treating this chronic condition and the DVA mental health care system has the potential to make significant advances in PTSD treatment. The bulk of what we know about PTSD comes from DVA funded research, training and clinical programs and psychologists have consistantly been at the vanguard of these treatment and research efforts.

While much is being done within the VA, we believe that much more needs to be done to address the unmet needs of this population. Before we discuss any program expansions that have been proposed by Representative Jontz and others, it is appropriate to look at the primary barrier to Veterans' receipt of PTSD services offered through the DVA health care system. PTSD is in the most basic sense, a "service-connected" condition and yet many veterans are in a frustrating and potentially life-threatening situation in which they have limited access to VA treatment services because they heve not been adjudicated as "service-connected." Because of the complexity of

eligibility determinations, thousands of veterans do not even have timely access to the proper DVA mental health care personnel for diagnosis and assessment and/or emergency services. A veteran suffering from severe PTSD can, according to DVA surveys, wait up to two years before ever receiving any meaningful treatment services.

Because of the DVA's responsibility and commitment to treating veterans suffering from PTSD, we believe provision should be made for the treatment of PTSD on a priority basis and for expedited access to assessment for PTSD at DVA health care facilities. This would eliminate the requirement that a veteran, who has been diagnosed as suffering from PTSD by an appropriate mental health professional, withstand the often lengthy formal adjudication of service connection in order to access DVAMC treatment.

Beyond the issue of a veteran's eligibility for treatment services lies the discussion of which services are available and which services should be available for the treatment of PTSD. Currently PTSD treatment is offered through a range of mental health care services within VHS&RA including acute inpatient care, residential and day treatment services, outpatient and Vet Center services. Again the concept of a comprehensive continuum of care is essential to ensure that mental health care is tailored to the individual veteran's needs, achieves desired results and is cost-effective.

H.R. 3037, introduced by Representative Jontz, recognizes the need for a continuum of mental health care services for PTSD treatment. We applaud this effort to take a comprehensive approach to expanding PTSD services. We are generally supportive of any needed expansion of the number of specialized inpatient units (SIPUs) and Vet Centers. We wish to emphasize, however, new Vet Centers or SIPUs should only be expanded to areas where services are lacking and the need has been demonstrated. While the language of H.R. 3037 specifies that Vet Centers are to be established only in cities where there are no such Centers, the bill is silent with respect to the location of additional inpatient units. In both cases, we strongly recommend that the Secretary be required to consider the density of the VA population in a given geographical area as well as the special needs of ethnic minorities and women. The findings of the Research Triangle Institute (RTI)

study reinforces the need for such sensitivity in providing services. For example, the prevalence rates for PTSD for Hispanic and black veterans is four times higher than for white and other veterans. The best approach to expanding SIPUs, Vet Centers and any other service related to the treatment of PTSD must include the flexibility to consider such factors and special needs.

We also encourage better coordination between Vet Centers, SIPUs and PTSD Clinical Teams (PCTs) to ensure that veterans with PTSD symptoms have access to DVA mental health care professionals who are trained to accurately diagnose PTSD. This would help address the issue, previously mentioned, of ensuring that PTSD is detected as early as possible. Such coordination, combined with priority access to treatment and an expedited adjudication process would greatly enhance the DVA mental health care system's ability to properly treat those in need of immediate care.

It is important to note that PTSD is often accompanied by the diagnosis of severe alcohol or substance abuse. Better coordination in all phases of and settings for PTSD mental health care should include increased Vet Center access to specialists, including psychologists who are trained in dual diagnosis of both PTSD and other disorders related to substance abuse. To this end, we encourage the use of DVA funds to create new PTSD Substance Abuse Disorders programs (PSUs) and the sharing of DVA staff and resources to ensure Vet Center participants have access to such trained mental health care teams of professionals.

In the spirit of providing a continuum of mental health care for PTSD Treatment, Rep. Jontz has proposed a pilot program under which the Secretary could contract for PTSD treatment and rehabilitative services in community-based treatment facilities. While we support any initiative to test new ways to address the treatment needs of veterans suffering from PTSD, we are concerned that such initiatives may divert already scarce DVA resources to the detriment of existing programs. The DVA mental health care system can gain useful knowledge about PTSD treatment while at the same time expand current services. In order to ensure accountability of this contract

program, the Jontz bill requires the Secretary approve the "quality and effectiveness" of the program whether it be a residential treatment facility, a halfway house or other community-based program. The Secretary must publish criteria by which quality and effectiveness is to be measured. We commend the inclusion of such accountability measures and also encourage the requirement of comprehensive treatment outcome evaluation to measure the actual success of any new PTSD program.

Finally, I wish to stress that any newly-created program or expansion of existing programs should be viewed as part of the ongoing efforts within the DVA to provide quality mental health care services. While we are aware that the Federal budget requires fiscal restraint we strongly urge that no new service take away from the operation of existing, effective services. We urge that any new program for the treatment of any veteran population have separate funds earmarked for implementation.

Another important issue addressed in H.R. 3037 is the need to coordinate efforts between the Department of Labor and the Office of Personnel Management to encourage employment opportunities for those who have have successfully completed PTSD treatment and rehabilitative services. We were pleased that Rep. Jontz included language of this nature in his legislation. We were not sure whether Rep. Jontz intended for this employment assistiance initiative to apply only to Veterans who had completed the pilot program treatment or whether such assistance would be provided to Veterans who had completed any DVA-PTSD treatment program. We encourge the application of such joint efforts for employment assistance to Veterans who have successfully completed <u>any</u> PTSD treatment program who have also been certified by a qualified mental health professional to be sufficiently rehabilitated to be employable. In addition, the current version of the bill would require such certification to be conducted by a "medical authority." We believe this requirement is unnecessarily restrictive and would exclude access to clinical psychologists who have extensive PTSD and general mental health experience and training. Psychologists are well-known among physicians and other mental health professionals, for their expertise in diagnostic assessments and are often called upon by physicians to conduct the assessments and diagnoses in PTSD cases.

As I have previously mentioned, an important consideration in ensuring access to quality mental health care services is the presence of qualified professionals serving in the DVA health care system. The DVA has experienced significant problems with respect to the ability to recruit and retain well-trained, highly qualified psychologists due to a variety of causes including inadequate compensation. Representative Jontz's bill recognizes the need to attract psychologists and other mental health professionals by attempting to include students of mental health professions in the VA scholarship program. We support any such efforts to address the shortage of qualified mental health care personnel for PTSD research and treatment.

Finally, we are generally supportive of the creation of an additional group to advise on PTSD issues as called for in the Jontz bill. We also support additional PTSD research. We wish to emphasize, however, that while we favor continued exploration of appropriate procedures for treatment of PTSD and other mental health problems, we urge the Subcommittee to resist attempts to standardize PTSD treatment modalities. We hope that any policy decisions regarding treatment take into account the individualized nature of mental health treatment. Qualified DVA mental health care professionals are able to prescribe individualized treatments to individual needs. Attempts to standardize treatment may result in the preclusion of methods that may work for some Veterans but not others. This concept of providing a continuum of care with multimodal treatment services has been supported and advanced by the Director of Mental Health Behavioral Science Service (VHS&RA), Dr. Paul Errera. We believe Dr. Ererra's approach to providing flexible, comprehensive mental health services offers a good working model for expansion.

In summary, I believe that there are a number of programs within the DVA mental health care system which bring hope and promise to Veterans suffering from a variety of serious mental disorders including PTSD. The APA and the AVACP pledge their continued support and cooperation in efforts to extend and refine such programs and to ensure the development of advances in treating PTSD and other psychological disorders afflicting our Nation's veterans. I thank you for giving us the opportunity to testify and I would be happy to answer any questions you and the members of the Subcommittee may have.

STATEMENT

OF

DANIEL H. WINSHIP, M.D.

ASSOCIATE DEPUTY CHIEF MEDICAL DIRECTOR

DEPARTMENT OF VETERANS' AFFAIRS

BEFORE THE

SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE

COMMITTEE ON VETERANS' AFFAIRS

HOUSE OF REPRESENTATIVES

June 28, 1990

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here this morning to discuss VA's delivery of mental health services. This hearing raises some important issues and we welcome the opportunity to share in the debate.

The Committee's agenda implicitly asks, for example, whether VA has the capability of meeting the needs of those psychologically scarred by combat or other profound stress. Your consideration of legislation on PTSD treatment also raises implicitly the question, does VA lack sufficient legal authority to provide needed services, or are there statutory impediments which require Congress' action?

At the same time, the Committee this morning becomes the first congressional panel to address through public hearings what has widely been viewed as a major mental health-care dilemma. VA and other health care systems nationwide face an unprecedented, and, in our view, untenable problem in attempting to simply purchase a recently-marketed drug, Clozaril, which holds promise for helping treat the most intractable of our schizophrenic patients.

Mr. Chairman, let me set a framework for discussion of these more specific issues by providing a capsule overview of our mental health programs.

Overview of VA Mental Health Care

VA provides mental health care services through each of its 172 medical centers. In Fiscal Year 1989, VA treated some 200,000 patients in the 146 psychiatry bed sections of its medical centers. In that same year our patients made more than 5 million outpatient mental health visits. These included visits to our mental health clinics, our 75 Day Treatment Centers, 34 Day Hospitals, 139 Outpatient Alcohol Dependence Treatment program and 51 Drug Dependence Outpatient programs. We provide mental health services ranging from counseling to rehabilitative work therapy to substance abuse programs. Among our fastest growing programs are those dedicated to the treatment of post-traumatic stress disorder (PTSD) (which, I will discuss in more detail below).

While devoting resources and energies in recent years to such problems as PTSD, we have also pioneered programs for the care of the homeless chronically mentally ill. Certainly VA has had much experience in the care of chronic mental illness. We estimate, that we provided care last year to some twenty-seven thousand veterans with a primary diagnosis of schizophrenia, for example.

Clozaril

VA thus viewed with real interest and expectation the anticipated availability of the drug clozapine. Research studies -- some reflecting clinical trials by VA investigators -- suggested that this drug offered hope for meaningful clinical gain in a segment of our schizophrenia patients for whom other medications produced little benefit.

As with many other medications, administration of clozapine is not free of risk for the patient. Some one to two percent of all patients treated with clozapine may experience a blood disorder, which, if undetected, could be fatal. Administration

of clozapine, therefore, necessarily requires appropriate patient monitoring by the provider. In an altogether unprecedented step, however, its manufacturer, Sandoz Pharmaceuticals Corporation, has tied purchase of this promising drug to purchase of a complicated, expensive blood testing system, the so-called Clozaril Patient Management System (CPMS). In other words, VA (and all other providers) can only obtain clozapine (marketed as Clozaril) by purchasing the drug and the company's monitoring system as a "package."

VA wishes simply to buy the drug Clozaril. We have no need to buy the CPMS or any related monitoring services. We have that capability ourselves and we have a duty to monitor these patients for any adverse side effects.

In our view, we would compromise the quality of our patient care if we permitted its fragmentation under CPMS. In essence, however, the manufacturer would require VA to purchase an obviously costly service we don't need which, at best, would duplicate what VA must do "in-house." The situation raises a troublesome question: since VA only has legal authority to contract for "necessary" services, may VA expend public monies for a service it does not need?

To resolve this issue and to respond to the manufacturer's concerns over monitoring compliance and need for a national data base, a team of VA specialists developed an alternative monitoring program, the VA Clozapine Management Protocol (VCMP). The protocol establishes a uniform, national "risk management" system for patients on this drug. All VA prescriptions for the drug, by protocol, would be limited to a seven-day supply. The system relies on specifically developed software programs for VA's decentralized hospital computer program (DHCP). This system verifies automatically that the patient's weekly blood test has been conducted and that there is a satisfactory white blood cell count prior to allowing VA pharmacists to enter prescriptions for this drug. If the white blood cell count is not present, or the

count is too low or trending downward, the prescription entry will be automatically "locked out." We believe that this software component answers any concern over, and assures, total monitoring compliance.

Use of this system would allow VA to provide good clinical care by assuring that the patient receives complete medical monitoring and that care is not fragmented. Additionally, it would assure that the patient received care in the most resource-efficient manner. Risk factors involved in clozapine therapy include heart disease, alcohol and substance abuse, and age. We recognize that VA patients represent a unique subset of patients who are frequently elderly and often have multiple medical conditions, including substance abuse-related conditions as well as heart disease. CPMS manages only for the risk of low white blood cell counts and does not manage for other potentially fatal adverse side effects. VA's monitoring protocol provides a mechanism for the comprehensive and complete medical management of the patient to assess and monitor for all adverse effects and to provide other therapy in addition to medication.

VA officials formally presented this protocol to the manufacturer at a March 28, 1990, meeting. In explaining this system, VA representatives reiterated a willingness to provide relevant epidemiological data to the company. Sandoz officials however, unequivocally refused to accept the VA monitoring system as an alternative to the CPMS for VA patients.

Given the VA's unique capabilities as a <u>national</u> health care provider and the exceptional monitoring system we have established for Clozaril patients, we find it difficult to accept the manufacturer's response that acceding to VA would require creating an exception for all others. Secretary Derwinski has conveyed that view to Sandoz's President and urged that the company reconsider its position. To date, Sandoz officials have remained rigid.

In our own effort to be responsive to the concerns of our patients and clinicians, we have provided guidance to assist those VA medical centers that may wish to bring clozapine onto their formularies. This guidance outlines the unique features of clozapine, including risk factors and indications for use in the VA patient population. It also indicates the need to accommodate the CPMS, at the cost of $9000 per patient per year. This also describes additional VA-specific monitoring requirements. An education program for VA clinicians on clozapine is also indicated. The VA Medical Center in Hines, Illinois, and Sandoz are in the process of negotiating a national product/service contract.

The decision to allow VA Pharmacy and Therapeutics Committees to consider adding clozapine to VAMC formularies does not imply an acceptance of CPMS as an ideal monitoring system. Nor does it imply a finding that the non-negotiable price for this "package" is reasonable or fair. To the contrary, our concerns about the use of Clozaril under the CPMS -- particularly its exorbitant cost, the needless duplication of services, and the potential fragmentation of care -- all remain. In reality, authorizing our medical centers to consider purchasing this drug is only a stop-gap measure. We do not anticipate that many of our medical centers will be able to justify extensive purchases of Clozaril. Indeed we hope that this hearing, escalating public concern regarding the marketing of this drug, and the manufacturer's experience in the marketplace will lead it to revisit its marketing and pricing policies on Clozaril.

In that regard, let me offer some additional perspective on the matter of cost. Early estimates projected that some 2,000 veterans with schizophrenia in the VA health care system would be candidates for clozapine therapy, at a cost of $18 million to VA for clozapine treatment (plus CPMS) alone. This estimate has some foundation, approximating the number of veterans with a primary diagnosis of schizophrenia hospitalized six months or

more in FY 1989. However, it may be a conservative estimate. As many as one third of schizophrenics may not respond optimally to medication over time, suggesting that there might be up to 9,000 candidates for clozapine in the VA system currently. Even if only 40 percent of these are helped by clozapine (as suggested in the United States clozapine trials) this would mean 3600 veterans on long term clozapine treatment at a cost of over $32 million per year for medication alone.

It's been suggested that the true costs of this therapy are much, much lower, because it would enable hospitalized patient to be discharged. Let me emphasize, however, that VA will not realize any substantial savings from decreased level of care for these patients. Bed service savings come from closing hospital beds, and this will not occur to any degree in the VA because these patients are spread throughout our system. Moreover, based on the field trials of clozapine, only 10 percent of respondents may be able to be discharged and even these will require ongoing supportive therapy. Pills alone are not sufficient treatment for schizophrenia.

Finally, an additional impact of the high cost of Clozaril under the CPMS is the risk of restriction of research on the product, which is essential to understanding its true value. A VA cooperative study on the effects of clozapine on treatment-resistant schizophrenia, in terms of clinical outcome and patient functioning, was developed by clinician-scientists on a VA-instituted Clozapine Task Force. This proposed study has received initial VA approval, but the costs of clozapine for the project, close to one million dollars, may well be prohibitive. Sandoz has indicated that it has no funds available to support such a study. If this continues to hold true, future research on clozaril in schizophrenia and comparative trials of clozaril and other new products to treat schizophrenia may be stifled.

In our view of these concerns, we welcome the Committee's oversight on this issue.

PTSD

Just as VA has, in our view, been a leader in confronting the issues posed by Clozaril's marketing, we have led the country in the development of clinical models to treat Post-traumatic Stress Disorder (PTSD), and in enlarging the health care community's understanding of that disorder.

PTSD as a consequence of war zone related experiences represents a priority for care by the Department of Veterans Affairs. VA concurs with the findings of the National Vietnam Veterans Readjustment Study (the RTI Study) not only in terms of the continuing current need for PTSD treatment services, but also in the increasing willingness of veterans with PTSD to seek care from VA. The NVVRS states that half of the Vietnam Theater veterans with PTSD who had received PTSD treatment at VA had done so in the past year. The number of individual veterans with PTSD discharged from VA inpatient services had increased from 5,377 in FY 1984 to 12,750 in FY 1989. Vet centers continue to see increasing numbers of veterans with PTSD, the number of first vet center contacts for PTSD increasing by 10 percent in FY 1989 over the previous year.

The optimal treatment for a chronic disorder such as PTSD is provided by a continuum of care with varying levels of care provided by different types of programs to match the changing needs of patients. Currently, VA's continuum of care for PTSD includes intensive inpatient care in 20 Specialized Inpatient PTSD Units (SIPUs), specialized outpatient care in 44 PTSD Clinical Teams (PCTs) and specialized counseling, rehabilitation and treatment services through 196 Vet Centers. In recognition of the clinical significance of disorders co-existing with PTSD, especially substance use disorders, VA has established four inpatient-based PTSD Substance Use Disorder (PSU) demonstration projects to provide concurrent treatment for these two disorders. In August 1990, from three to six outpatient based Substance Use Disorder/PTSD Teams (SUPTs) will be designated in

response to a Request for Proposals released this month. Current VA MEDIPP program guidance encourages proposals for new inpatient and outpatient PTSD programs. Ongoing systemwide PTSD education programs train clinicians in general mental health programs as well as those in the above noted specialized programs. This is essential because over 60 percent of PTSD discharges come from VA facilities that do not have designated specialized inpatient PTSD programs.

VA has also had the benefit of the studies and recommendations regarding PTSD provided by the Chief Medical Director's Special Committee on PTSD. The VA has adopted many of the committee's recommendations furnished in its six annual reports.

Weighing the competing demands for resources, and the base from which we started just a few years ago, the Department has made considerable progress in developing a sound health-care infrastructure for PTSD care and conducting continuing medical education to meet veterans' needs.

Legislation to Expand PTSD Programs

Mr. Chairman, you have also asked for VA comments on H.R. 3037, a bill which would mandate that VA carry out a series of actions aimed at expanding PTSD services. The measure is not, of course, an appropriations bill.

H.R. 3037 would direct VA to

-- increase over some four years the number of vet centers (by 40) and the number of inpatient PTSD treatment facilities (by 30);

-- allocate $10 million for PTSD contract services; and

-- conduct a research program to determine the most effective modes of inpatient and outpatient PTSD treatment, and to coordinate and standardize such treatment in the VA.

This bill would also require VA to establish a permanent advisory committee with which the Secretary would be required to regularly consult regarding wartime and post Vietnam-era veterans and particularly Vietnam-era veterans and their needs for and administration of any VA benefits. This committee would be charged to meet regularly and provide annual assessments and reports.

The bill would also direct VA to encourage mental health professionals specializing in treating PTSD, to participate in its scholarship and tuition reimbursement programs. Finally, the bill would authorize VA to conduct a pilot program under which it could contract for halfway house and other residential care of veterans suffering from PTSD.

VA certainly places a high priority on treatment of veterans suffering from PTSD. As our testimony indicates, we have seen very substantial growth in treatment programs and other initiatives in the years since the profession's recognition of PTSD as a psychiatric diagnosis. We recognize, too, the implications of the National Vietnam Veterans Readjustment Study, which concluded that some 479 thousand Vietnam veterans have PTSD. One-fifth of that group has received VA care. While those data show that large numbers have apparently not sought VA care, it does not follow that legislation is needed.

VA shares many of the goals reflected in this bill. Nevertheless, VA has sufficient statutory tools to provide PTSD services. Thus, we do not support enactment of legislation. But this bill raises several other conceptual problems. While we would be pleased to discuss these and related points in more detail, let me highlight a number.

1. Expansion of PTSD treatment facilities: In its prescriptiveness, this measure overlooks the clinical importance of VA's maintaining an array of treatment services having the flexibility to meet patients' varying needs. Rather than

focusing only on specialized inpatient units and vet centers, VA seeks a mix which also includes dual diagnosis programs and PTSD clinical teams to provide ambulatory treatment and consultations.

2. Mandating prescribed minimum funding for contract care: VA-furnished care is simply more economical from a cost/visit standpoint. The enactment of this provision would in all likelihood require VA to take funds away from a more cost/effective service.

3. Pilot program on PTSD: Unlike certain other VA programs on which this provision is modelled, PTSD treatment is highly specialized. VA rather than community providers have the broadest degree of expertise in treating it. Establishing such a pilot would not be cost-effective.

4. Establishment of an Advisory Committee on Readjustment: VA's PTSD and other activities already have effective oversight by advisory and other committees. Among the approximately thirty-five advisory committees currently operating in VA are the Secretary's Advisory Committee on Readjustment of Vietnam veterans (membership from non-VA experts) and the CMD's Special Committee on PTSD (membership from VA experts). VA does not support the creation of a new one that would duplicate the functions served by those boards now examining these areas.

We estimate that enactment of H.R. 3037 would result in additional costs of some $30 million in the first year, and approximately $192 million over five years.

Mr. Chairman, this completes my testimony. My colleagues and I would be pleased to respond to any questions.

STATEMENT OF
FRED D. GUSMAN, M.S.W.
DIRECTOR
CLINICAL LABORATORY AND EDUCATION DIVISION
NATIONAL CENTER FOR PTSD
BEFORE THE
COMMITTEE ON VETERANS AFFAIRS
UNITED STATES HOUSE OF REPRESENTATIVES
JUNE 28, 1990

As the Director of the Clinical Laboratory and Education Division of the National Center for PTSD it is with pleasure that I have witnessed the change in course of what were once limited efforts to what is now accelerated and comprehensive treatment in PTSD.

Following the Vietnam War some veterans did receive treatment from various VAMCs, however, there was no coordinated effort throughout the Veterans Health Service and Research Administration (VHS&RA), nor special acts or funds to support these efforts addressing war-zone related stress. Since the beginning of its existence, the Department of Veterans Affairs has had the huge task of providing both medical and psychiatric care to its veterans. It is extremely difficult to single out a special group without overlooking the needs of another. During the past 4 years Congress has provided financial support to initiate comprehensive and creative treatment for PTSD. Due to this financial support the Department of Veterans Affairs has been able to address and establish the following PTSD services:

* Specialized Inpatient Units (SIPUs)
* PTSD Clinical Teams
* PTSD-Substance Abuse Units
* Vet Centers
* The National Center for PTSD
* Substance Use/Post-Traumatic Stress teams (SUPTs) (newly proposed)
* Special Populations - Public Law 101-144 designated the Department of Veterans Affairs, through the National Center for PTSD "to study how best to provide outreach and treatment to minority (including women) Vietnam veterans"

Overview

I would like to provide you with a brief history of PTSD treatment provided by the VHS&RA:

When the first group of Vietnam veterans sought treatment at local VAMCs, they encountered a medical system unprepared to serve their unique needs. Due to the lack of appropriate services for these veterans, many became outraged and turned to the media to present their cause. Their message reached VAMCs nationwide, and slowly, special treatment programs began to be developed to serve this unique patient population.

In 1978, the first Specialized Inpatient PTSD Unit (SIPU) in the VA system opened its doors at the Palo Alto VAMC, Menlo Park Division, CA. Within five years, six more VAMCs established specialized units: Tomah, WI, Bay Pines, FL, Coatesville, PA, Northampton, MA, North Chicago, IL, and Topeka, KS. Historically, there has not been a coordinated effort in the size of the programs and treatment offered by the SIPUs. This is primarily due to three factors: 1) the limited knowledge base in respect to the treatment of PTSD; 2) these programs were initiated by local interest without built-in program evaluation; and 3) these programs were funded by the limited financial resources of the local

Medical Center's budget (Only Phoenix and Tacoma, received special funds from VACO for their implementation, while some already implemented programs received additional funds to augment their local medical center funding). These three factors can account for multiple problems in the delivery of inpatient treatment for PTSD, such as:

a. diversity in staffing patterns
b. variance in bed size
c. treatment based on individual and local perceptions of the Vietnam veterans' needs
d. minimal research activities
e. inability to address the multiple problems related to PTSD (e.g., co-morbidity, PTSD-Alcoholism, family issues, etc.)
f. inconsistency in catchment area served
g. waiting list incongruity (e.g., one waiting list for screening/evaluation and another for admission)

In addition, the SIPUs have been vulnerable due to local, regional, and national budgetary constraints. I would like to commend those Medical Centers that have been successful in providing services for veterans suffering from PTSD while proceeding to meet the needs of all veterans utilizing their facilities. During the last 4 years congressional support through the Department of Veterans Affairs has provided some medical centers with additional funds to develop and maintain ongoing services for veterans suffering from war-zone related stress.

In 1984 the Subcommittee on Hospital and Health Care of the House Committee on Veterans Affairs, met for the purpose of reviewing and assessing the VHS&RA's position in providing services to Vietnam Veterans. Later that year, Public Law 98-528 was enacted (1984). This Public Law designated the Chief Medical Director's Special Committee on PTSD whose purpose is "to comment on the capacity of the VA to recognize, diagnose, treat, educate, and conduct research on PTSD". In addition, the Special Committee is to advise the CMD regarding policy development and service coordination for the diagnosis and treatment of PTSD (Preamble - CMD's Special Committee on PTSD, First Annual Report, 1985).

Section 110 of Public Law 98-528 also designated "specialized units for the diagnosis and treatment of PTSD ..."(page 6, Agency's Report on the Implementation of Section 110, PL 98-528, PTSD - 1986-87). With this enactment, the CMD designated 70 FTEE and approximately 2.6 million in salary dollars for implementing and augmenting Specialized Inpatient PTSD Units.

Current Status: Specialized Inpatient PTSD Units

The following 16 Medical Centers house the Specialized Inpatient PTSD Units:

1. Augusta, GA
2. Bay Pines, FL
3. Buffalo, NY
4. Coatesville, PA
5. Little Rock, AR
6. Lyons, NJ
7. Montrose, NY
8. Northampton, MA
9. North Chicago, IL
10. Palo Alto, CA
11. Phoenix, AZ
12. Tacoma, WA
13. Togus, ME
14. Tomah, WI
15. Topeka, KS
16. Waco, TX

Four new Specialized Inpatient PTSD Units (SIPU) have been funded by Central Office:

1. Salem, VA
2. New Orleans, LA
3. West Los Angeles, CA
4. Waco, TX

These programs should begin to receive funding by July 1, 1990. Although the Waco, TX SIPU was implemented from local Medical Center dollars, their funding is being augmented by Central Office.

Current Status

The following information was collected on the SIPUs during the months of May and June of 1990 (more detailed data on individual SIPUs available upon request):

Bed Size

Bed size of program range from 12 beds to 106 beds with an average of 26 beds.

Waiting List

As of May 1990, there were approximately 332 veterans waiting for screening and 576 waiting for admission to treatment. The length of wait ranges from as little as two weeks to as long as one year for admission for treatment.

Referral Sites
Patients are referred to the SIPUs from other VAMCs, Vet Centers, private practitioners, self-referral, etc.

* 53% of all referrals come from other VAMCs
* 36% of all referrals come from Vet Centers
* 11% of all referrals come from other sources

Staffing

Staffing varies with program size, however, professionals from the nursing field (RN, MS, RNs, RNP, LVN, LPN, NA, etc) dominate the number of staff members. Some programs only have .5 M.D. with which they often have to share with another psychiatric or substance abuse program.

Programs have been creative in the types of personnel used for treatment while operating with a tight budget. However, more information is needed regarding the best staff-to-patient ratio.

Areas of Concern

Although we are moving in the right direction in regards to the treatment of PTSD, there are some issues of concern:

1) **geographic disproportion** - The majority of specialized PTSD services tend to be located in the eastern part of our country. This does not coincide with the location of the veteran population;

2) **waiting lists** - Some SIPUs have waiting lists for only admission while others also have a separate one for screening/evaluation. These lists can be as long as eight months long. This has a detrimental effect upon the veteran in need of inpatient treatment.

3) **staffing** - Survey findings show that there is such a variance in staffing. It is imperative to have adequate and well trained staff to serve this population.

4) **chronicity** - As the patient population gets older and co-morbidity becomes more of a problem in treating PTSD, the chronicity of this patient population will require the development of treatment modalities to prevent a new population in need of long-term institutionalized care.

5) **resource allocation model (RAM)** - Through RAM, the designation of a limited amount of money and time with which to treat PTSD (although it does not have its own DRG) has applied pressure to SIPUs to "game" the system in order not to be losers. This can effect the overall treatment and can result in the loss of resources.

6) **outcome research** - There has been little outcome research on inpatient treatment. Outcome research needs to be supported in order to determine the effectiveness of treatment.

PTSD CLINICAL TEAMS

Public Law 98-528 set the stage for the organization and establishment of a "Special Committee" to "...carry out a continuing assessment of the capacity of the Veterans Administration to provide diagnostic and treatment services for PTSD to veterans eligible for health care furnished by the Veterans Administration" (October 19, 1984). Following this congressional mandate, the newly established Chief Medical Director's (CMD) Special Committee on Post-Traumatic Stress Disorder (PTSD) met in January of 1985. The committee recommended that VA Medical Centers set up outpatient PTSD Clinical Teams (PCTs) and that each be allocated at least two FTEE, one of which was to be a psychiatrist experienced in the diagnosis and treatment of PTSD. These PCTs were to provide: 1) direct clinical care; 2) integrate treatment offered in Vet Centers, hospital programs (inpatient and outpatient care), and Specialized Inpatient PTSD Units in order to ensure continuity of care for all veterans; 3) provide consultation-liaison to medical and surgical units; 4) supervise educational programs on PTSD; and 5) monitor utilization patterns of patients with PTSD (Page 30, I Resource Allocation, First Annual Report of the Chief Medical Director's Special Committee on PTSD, January 25, 1985).

The Veterans Health Service and Research Administration (VHS&RA) felt that this recommendation was too large-scale to implement. It therefore recommended the implementation of 15 sites as a pilot project:

1. Minneapolis, MN
2. Dallas, TX
3. Seattle, WA
4. Boston, MA
5. Brooklyn, NY
6. Chicago, IL
7. Hines, IL
8. New York - Manhattan, NY
9. Washington, D.C.
10. Philadelphia, PA
11. Long Beach, CA
12. Denver, CO
13. San Francisco, CA
14. West Los Angeles, CA
15. Allen Park, MI

In 1989, a Request for Proposals was sent to all VAMCs for the initiation of additional PCTs. A total of 92 VAMCs submitted proposals in response. At this time, the original 15 PCTs were evaluated as to their fulfillment of their mandate. Six of the original PCTs were discontinued.

In total, 24 Medical Centers were selected as hosts of PCTs. In addition, in 1990 funding was obligated for another 20 PCTs. The 44 PCTs are as follows:

1. Albuquerque, NM
2. Baltimore, MD
3. Battle Creek, MI
4. Boise, ID
5. Boston, MA
6. Brooklyn, NY
7. Buffalo, NY
8. Canandaigua, NY
9. Charleston, SC
10. Cheyenne, WY
11. Chicago (WS), IL
12. Chillicothe, Oh
13. Clarksburg, WV
14. Dallas, TX
15. Denver, CO
16. Fayetteville, NC
17. Gainesville, Fl
18. Hines, IL
19. Honolulu, HI
20. Jackson, MS
21. Kansas City, MO
22. Loma Linda, CA
23. Los Angeles (OPC), CA
24. Marion, IN
25. Miami, FL
26. Minneapolis, MN
27. Mountain Home, TN
28. New Orleans, LA
29. Oaklahoma City, OK
30. Perry Point, MD
31. Philadelphia, PA
32. Phoenix, AZ
33. Pittsburgh, PA
34. Portland, OR
35. Providence, RI
36. Salt Lake City, UT
37. San Antonio, TX
38. San Francisco, CA
39. San Juan, PR
40. Seattle, WA
41. Togus, ME
42. Topeka, KS
43. Tuskegee, AL
44. White River Jct., VT

The Northeast Program Evaluation Center (NEPEC) is currently collecting data from the PCTS in the following areas:

Operations

- *number and type of FTEE hired
- *veterans seen and treated

Patient Demographics

- *age
- *ethnicity
- *employment history
- *military info:
  - era of service
  - service connection
  - combat exposure
- *education
- *marital status
- *diagnosis

NEW DIRECTIONS

With the advent of special funding for PTSD services over the past few years, VHS&RA and the leadership of Paul Errera, M.D., and his clinical and administrative staff from Mental Health and Behavioral Sciences Service (MH&BSS), VACO, has been able to develop and implement a responsive approach in the delivery and treatment of PTSD. These approaches include: 1) instituting an ongoing program evaluation for PTSD services; 2) developing national educational programs; 3) providing administrative guidance to the field; 4) initiating networking and communication between each SIPU and PCT site; and 5) developing program guidelines for inpatient and outpatient treatment. Additionally MH&BSS has supported the National Center for PTSD in carrying out its mission.

For example, in order to further communication regarding inpatient and outpatient care for PTSD, MH&BSS has initiated monthly conference calls for the PCTs and more recently in May 1990 initiated calls for the SIPUs. These calls are sponsored and supported by: the Director and Associate Director for Psychiatry of Mental Health and

Behavioral Sciences Service, the Northeast Program Evaluation Center and the National Center for PTSD. The purpose of these calls is to address all areas relating to PTSD treatment: program evaluation, clinical issues, and educational needs.

Role of the National Center for PTSD

As mandated in Public Law 98-528, the National Center for PTSD (Appendix A) "carries out and promotes the training of health care and related personnel in, and research into the causes and diagnosis of PTSD and the treatment of veterans for PTSD, and serves as a resource center for, and promotes and seeks to coordinate the exchange of information regarding all research and training activities carried out by the Department of Veterans Affairs, and by other Federal and non-Federal entities, with respect to PTSD."

In response to this mandate the Clinical Laboratory and Education Division of the National Center for PTSD will provide educational support to all Specialized PTSD services and all VAMCs providing PTSD services.

Conclusion

I would like to acknowledge and thank Congress for its continued support to VA in the area of PTSD.

Although the VHS&RA has been moving forward in its provision of comprehensive and creative treatment for PTSD, we are not at the end of the tunnel. The National Vietnam Veterans Readjustment Study (conducted by the Research Triangle Institute) found that there are still over 800,000 veterans who suffer from full-blown or partial PTSD. The field of PTSD is rapidly advancing in the areas of assessment, diagnosis, treatment, and research. It is imperative that this new and important information that is continually being developed from the field be disseminated through appropriate educational activities.

In closing, I wish to thank the chairman and the members of the House Committee on Veterans Affairs for providing me with this opportunity to speak on behalf of the VHS&RA inpatient and outpatient treatment of veterans suffering from PTSD.

TESTIMONY OF

THE CHIEF MEDICAL DIRECTOR'S SPECIAL COMMITTEE
ON POST-TRAUMATIC STRESS DISORDER

BEFORE THE

U.S. HOUSE OF REPRESENTATIVES

Committee on Veterans' Affairs
Subcommittee on Hospitals and Health Care

June 28, 1990

Presented by

Spencer P. Falcon, M.D.
Chairman, Chief Medical Director's Special Committee
on Post-Traumatic Stress Disorder
and
Chief, Psychiatry Service
Ann Arbor VA Medical Center

I am Spencer P. Falcon, M.D., Chief of Psychiatry Service at the VA Medical Center in Ann Arbor, MI, and Chairman of the Chief Medical Director's Special Committee on PTSD. I am pleased to appear before the Committee today to comment on the capacity of the Department of Veterans Affairs (DVA) to deliver mental health care services in general, with particular reference to the treatment of veterans suffering from post-traumatic stress disorder (PTSD). I'll also comment on the potential impact of prescription of the drug clozapine on the availability of mental health services within DVA. In many ways, it is appropriate that these issues be discussed together, in that both PTSD special programs and the possibility of funding clozapine therapy have been seen as potential enhancements or additions to the basic core mental health funding that is available through DVA. A concern with this type of new or dedicated activity is that it is at times a redirection of old funding, and therefore could potentially have an adverse impact on other parts of the total mental health care available.

The Special Committee has been in existence since 1984, when PL 98-528 mandated its mission to assess the capacity of the VA to provide diagnostic and treatment services to veterans with PTSD; and to advise the CMD regarding the development of policies, and the coordination of services for PTSD. The Special Committee on PTSD has been and continues to be committed to this

effort. The work of the Special Committee has been documented in six annual reports that were submitted to the CMD and Congress, and which include a large number of recommendations.

Substantial progress has been made in the availability of high-quality PTSD treatment services within DVA over the past decade. In many ways this evolution represents a collaboration between the Department and Congress, with legislation going back to the initial Readjustment Counseling Service (RCS) legislation of 1979, encouraging DVA to be more proactive in its provision of mental health care to Vietnam era veterans, and to veterans with combat-related stress from all wars. This substantial progress has, I believe, resulted in the development of a continuum of care needed by these veterans, which includes the outreach operations of the Vet Centers, the outpatient PTSD Clinical Teams (PCTs), the Specialized Inpatient PTSD Units (SIPUs), and the PTSD/Substance Abuse Units (PSUs). Each year has seen an enhancement of PTSD programs resulting from legislation and from a growing awareness by the clinicians and administrators within DVA of the critical importance of PTSD among our population.

Since 1984, a number of recommendations from the Special Committee have been associated with action by DVA or in legislation to provide PTSD treatment services, such as:

* Recommended creation of PCTs at each VAMC over a 5 year period; led to VACO funding of 15 PCTs in 1987 that subsequently evolved through new appropriations to larger numbers (44);

* Recommended improving funding of research on combat-related PTSD; by 1988 there was a 29% increase in funding for PTSD research: a 50% increase in VACO funded projects, and an 11% increase in locally funded projects compared with 1986 levels. In addition, there was Congressional support for PTSD of $150,000 annually for educational programs;

* Recommended increased clinical collaboration between Vet Centers and VA medical centers; there has been a more effective and coordinated deployment of resources to provide health care and readjustment services to veterans and their families;

* Recommended that all veterans with diagnosed war zone induced PTSD be included in DVA's non-discretionary workload in order to improve consistency and continuity of care, as well as to enhance the reciprocal referral process between Vet Centers and VAMCs. This became VA policy in February 1990, and removes an important barrier to care for PTSD patients;

* Recommended developing national standards for screening admissions, setting staffing standards, and developing dual diagnosis programs for patient with PTSD and other

concurrent disorders, with special attention to alcoholism/substance abuse. There is an ongoing collaboration of the Special Committee and Mental Health & Behavioral Sciences Service (MH&BSS) to develop national standards for inpatient PTSD units, and the initiation of PTSD/substance abuse units;

* Defined missions and functions of a DVA National Center for PTSD; participated in developing the Request for Proposals process to identify the site for the National Center for PTSD. In 1989 the new National Center for PTSD was funded as a consortium with the executive offices at the VAMC in White River Junction, VT; and encompassing programs in West Haven, CT; Palo Alto (Menlo Park), CA; and Boston, MA;

* Initiated the process of developing a comprehensive database on all VA PTSD activities. This evaluation process has been supported by funds from PL 100-404, and will be conducted by the Northeast Program Evaluation Center (NEPEC) at VAMC West Haven, CT, directed by Robert Rosenheck, M.D. The Special Committee will continue to monitor PTSD treatment units through this system.

The 1988 National Vietnam Veterans Readjustment Study (NVVRS) report shows that over the course of their lives, approximately half of the 3.14 million Vietnam theater veterans have experienced clinically significant stress reaction symptoms, including 27.9% of Hispanic, 20.6% of Black, and 13.7% of white/other Vietnam theater veterans. Despite this, the NVVRS data show that approximately 90% of the estimated 480,000 veterans with current PTSD, and 80% of the estimated 963,000 veterans with lifetime PTSD, have never used VA mental health resources. This information clearly indicates that further work must be done to ascertain the extent of unmet clinical need for Vietnam theater veterans who suffer from psychiatric sequelae to war-zone stress.

The Special Committee has a particular interest in the NVVRS study and in characterizing the unmet clinical need by veterans from all periods who have PTSD. DVA data on these treatment patterns is focused on inpatient services using the Patient Treatment File (PTF), as there is no similar coding and data entry process for outpatient care. Therefore, in 1986 a four-week survey was conducted by the Special Committee and the Great Lakes Regional Health Services Research and Development (HSR&D) Field Program, in conjunction with MH&BSS and RCS. All veterans who received outpatient care in Mental Health Clinics and Vet Centers were surveyed to determine the extent to which PTSD

patients are recurrent users of VA services, and to characterize the overall status of veterans treated by DVA for PTSD. A similar survey will be conducted in October 1990.

The Special Committee is also working with HSR&D on the development of a longitudinal database that will provide a basis for recommendations on sites and types of needs for future capital distributions. This resource blends information from our outpatient surveys with serial information from the inpatient PTFs in order to identify demographics and prevalence in standardized geographic areas. In addition to findings on utilization of VA services, this database will be able to provide information on chronicity, on outcome of care as based on the frequency of care for various problems, on the geographic movement of patients, and on the extent to which PTSD has been recognized over the years.

The findings from the NVVRS support the concept of PTSD as a chronic disorder. As we look at the life history of veterans, we see recurrences or a persistence of symptoms over decades. We must recognize that our commitment to these veterans will be continuous, and that their condition cannot be completely treated by one episode of care. We must also recognize that this has substantial implications for the funding of VA resources.

The current work that the Committee has undertaken is aimed at fully demonstrating where in the country, and in what clinical setting (Vet Center, PCT, SIPU), the needs of veterans with PTSD are being met, and in what areas they are not being met. We must, I believe, plan effectively for our current and new programs so that we can have true continuity of care, with access of veteran patients to not only Vet Centers and PCT programs, but also to regionally distributed tertiary referral centers, the special inpatient units. We must also continue to assure accountability for these program enhancements.

Even with the enhancements for treatment of PTSD and special funding for substance abuse treatment, the core mental health programs are deteriorating. The Resource Allocation Methodology

(RAM) created incentives for increasing the number of episodes of care and shortening lengths of stay. From 1984-87, psychiatry's LOS decreased 34.6% [from 47.7d to 31.2d]. As the lengths of stay for psychiatric admissions were lowered under the RAM, the patients became more complex and the staffing on these wards did not increase.

Between 1984 and 1987, the percentage of discharges from psychiatry bed sections of patients having dual diagnosis conditions involving serious psychiatric disorders in addition to alcohol and other substance abuse disorders, had increased from 48.5% to 74.3% These patients pose more complex treatment problems requiring a higher level of care, and therefore a greater demand on available resources. It must be recognized that optimal services for veterans with psychiatric difficulties will be provided only through a simultaneous concern with maximizing efficiency and clinical effectiveness.

A primary limiting factor in the treatment of veterans with PTSD has been continuing difficulty in the recruitment and retention of qualified psychiatrists. As an example, 34% of the psychiatrist positions in the PCTs were still vacant at the end of March 1990. The effect of these high vacancy and turnover rates has been as devastating to our treatment of veterans suffering from combat stress disorders as our 20% vacancy rates have been on other psychiatric patient care services.

The Special Committee feels very strongly that with adequate funding, safeguards, and organizational support, that DVA has an opportunity to achieve national pre-eminence in the field of PTSD through the research and education endeavors of its National Center for PTSD. The National Center has unique capabilities and the scientific leadership to develop effective techniques for the treatment of patients with PTSD, and to evaluate the outcomes from treatment based on the various ethnic and diagnostic populations. It is essential that clinically useful applications develop from this research.

The Special Committee is dedicated to assuring that the most current information is used to direct resources towards provision of the most effective treatment programs for our veteran patients with PTSD. PTSD may be complicated by other psychiatric disorders including alcohol and substance abuse, as well as long-term adjustment problems in critical areas of life functioning including employment, educational development, and family life. The programs available today are the foundation for the continuum of care needed by our veterans suffering from war zone stress.

OUTPATIENT PROGRAMS FOR THE TREATMENT OF PTSD

VET CENTERS

There are 196 Vet Centers, with at least one in each state, Puerto Rico, the Virgin Islands, and Washington, D.C. Although Vet Centers were never intended to provide the range and sophistication of treatment alternatives that are only available in VA medical centers, they have provided a combination of services within a psycho-social context that includes war debriefing, individual and group therapy, crisis intervention, marriage and family counseling, special outreach efforts to minorities, Agent Orange liaison, vocational counseling, social service networking, and community liaison.

The Special Committee has made specific recommendations for increasing the collaboration and continuity of care between the Vet Centers and the VA medical centers. The Vet Centers have an important historical position and an ongoing role in the provision of service to the Vietnam era veteran. The matching of a patient with the most appropriate treatment setting has become the state-of-the-art question in clinical delivery. The Vet Center treatment site, either as sole source of clinical intervention, or functioning in concert with a VAMC for pre- and post-hospital care, is the type of treatment model now being developed in the private sector.

PTSD CLINICAL TEAMS (PCTs)

The Special Committee continues to recommend that a PTSD Clinical Team (PCT) exist at least in every medical care facility that has a psychiatry or psychology service. The average annualized support for a new PCT is 4 FTEE ($231,000 for salary), and $1,500 in other funds.

Currently there are 44 PCTs around the country. These teams function to meet the clinical outpatient needs of veterans with PTSD through thorough evaluation and assessment, counseling and psychotherapy focused on central PTSD issues, and active community follow-up and intervention for veterans who have undergone evaluation and treatment. A part of the mission of the PCTs is to collaborate with the Vet Centers in order to enhance the continuum of care philosophy. The PCTs also provide preliminary treatment of concomitant psychiatric disorders prior to initiation of PTSD-specific treatment.

Data on PCT activities collected during the first six months of this fiscal year show that Vietnam veterans accounted for 88.2% of the veterans formally evaluated. Almost half of these veterans (48.7%) were non-Service Connected.

INPATIENT PROGRAMS FOR THE TREATMENT OF PTSD

The vast majority of veterans diagnosed with PTSD who are discharged from inpatient care are treated on general psychiatry units, not on units specializing in the care of veterans with PTSD. Inpatient treatment for PTSD has increased from 5,377 unique inpatients in 1984, to 10,108 in 1987, and preliminary PTF data from 1988 and 1989 show similar increases. This increased number of patients treated for PTSD is evidence of the increasing awareness of clinicians within DVA of PTSD as a treatable psychiatric condition. Vet Centers and PCTs play a large role in this increasing availability, providing pre- and post-hospital care, and community access to the VAMCs.

SPECIALIZED INPATIENT PTSD UNITS (SIPUs)

While a 2-3 week general psychiatric hospitalization can help to de-escalate a veteran in crisis, it is inadequate for the population of veterans with PTSD who require the intensive treatment provided in SIPUs.

In 1989 there were 423 beds assigned to 16 SIPUs (in 16 states) around the country, with 4 new units to be added in FY 90, and an average national daily census on these units of 385 veterans with PTSD. All of these units have a waiting list for admission ranging from several weeks to one year. These units serve veterans from beyond the Primary Service Area (PSA) of their VA medical centers, thus there are also limitations in the ability to provide pre-admission screening and assessment, marital and family involvement in treatment, or coordinated transition to outpatient aftercare for community re-entry.

The Special Committee continues to recommend that in order to meet VA's priority to provide quality care in a timely manner to veterans suffering from service-related disabilities, that there be adequate access to these special programs. Currently these programs are largely locally supported, and at times can be experienced as a financial burden.

PTSD/SUBSTANCE ABUSE PROGRAMS (PSUs)

There is a consensus that 50-70% of Vietnam era veterans with PTSD suffer from the comorbid conditions of psychiatric illness and alcoholism or substance abuse. The PTSD/Substance Abuse Unit (PSU) program directs treatment so that a veteran may overcome the substance abuse problem while receiving treatment for PTSD. Four PSUs were funded in FY 89, and have an average annualized support per PSU of $263,237 for salaries, and $1,500 in other funds.

The Special Committee is concerned that funding under RAM has been a disincentive to the operation of inpatient PTSD treatment units, and continues to recommend an alternative support methodology. It is important that we have adequately

supported regional/national centers of excellence where a veteran with PTSD may receive treatment when other attempts (Vet Centers, PCTs, general psychiatric inpatient care) have failed.

The Special Committee is very aware of the staggering numbers from the NVVRS study of veterans in need of treatment for PTSD. Many of the program initiatives detailed above are services intended for these veterans. All good medical care programs provide this spectrum of care that we are working to achieve. MH&BSS and RCS recognize this as reality. We also recognize that we cannot have PTSD care available at the expense of or in lieu of care for other veteran patients with mental illness and substance abuse problems.

CLOZAPINE

In February 1990, clozapine, an antipsychotic drug for the treatment of schizophrenia, became available in the U.S. through Sandoz Pharmaceutical Corporation exclusively. Administration of the drug poses some risks of a serious blood disorder, accordingly, appropriate clinical care would call for careful patient monitoring, including weekly blood testing. The Sandoz Pharmaceutical Corporation has developed a complicated and quite expensive system to perform such blood testing, the Clozaril Patient Management System (CPMS), that is tied to the purchase of clozapine and results in an annual cost per patient of $9,000. The CPMS system includes exclusive contractual agreements between Sandoz Pharmaceutical Corporation; Caremark, a national home health care company whose employees serve as case managers and draw weekly blood samples from patients under treatment; and a national laboratory which performs the blood count and reports to the case manager, Roche Laboratories. Therefore, clozapine can be obtained only by purchasing the drug and the entire monitoring system as a package.

The exclusion of clozapine from the standard VA psychiatric mental health delivery system, and the requirement to use the CPMS, have very far-reaching results in compromising the quality and continuity of care for veteran patients. Schizophrenic

patients form a large portion of our inpatient and outpatient care delivery. Patient Treatment File data from 1989 indicate that there were 65,000 discharges through DVA with a primary or secondary diagnosis of schizophrenia. Included in this were 47,000 discharges with a primary diagnosis of schizophrenia only, so that it is certain that those admissions were directly related to and as a direct result of the schizophrenic illness of those patients. In the 1986 Mental Health Outpatient (MHOP) Survey, it was learned that approximately 30% of veterans being treated in VA Mental Health Outpatient Clinics nationwide had a diagnosis of schizophrenia. The schizophrenic population is one, I believe, to which the psychiatrists and the psychiatric programming of DVA has directed significant attention.

Many of the individuals with chronic schizophrenia have only intermittent or relatively brief hospitalization, while others have long and protracted hospitalizations. All of them have a disease characterized by its chronicity, and long term relationship with mental health providers in DVA.

DVA already has a full and complete capability to provide all the services that are considered to be essential under the prescribing protocol for clozapine. Moreover, DVA has already developed a protocol that is an alternative to the CPMS, in recognition of the fact that monitoring should be performed by the patients' primary health care provider, the VA, to assure that the patient receives complete medical monitoring, and that the care is not fragmented. This monitoring is not unique for us. Many of the pharmaceuticals we currently use require some degree of patient monitoring. Regular Pro-thrombin times are standard in anticoagulant therapy. Frequently used medications in psychiatry such as Lithium or Tegretol require periodic blood testing to look at either levels of the drug present in the blood, or to look at effects on the hematopoietic system from taking the drug. Psychiatry Services regularly do blood levels on tricyclic antidepressants, and on neuroleptic or antipsychotic medications.

Looked at entirely from a quality of care standpoint, the requirement to utilize this external vendor to have the drug available will substantially compromise the quality of care. One of the characteristics of our veteran patients is that they don't have one diagnosis. From studies that we have done with many of our chronic schizophrenic patients, we find multiple co-morbidities, either co-existent neurological problems, other medical problems that have to do with illnesses of the cardiovascular system, pulmonary system, and/or urinary tract. As our population of veterans ages, the presence of these multiple co-morbidities becomes more frequent. It is not uncommon in our setting to be providing treatment for a veteran patient for a primary psychiatric illness, such as schizophrenia, along with treatment for cardiac disease, hypertension, diabetes, etc. One can see that in the presence of a complex treatment system, that if you take out one blood test and one case manager and remove that from the total patient care profile, you will substantially compromise that patient's care.

In addition to these concerns, there is the concern as a responsible psychiatrist and as the Chief of a Psychiatry Service responsible for the care of all individuals treated on that service. Over the last ten years, I have developed a degree of assurance and personal and professional knowledge of our laboratory at the Ann Arbor VAMC, and in our MHOP clinic staff who function as "case managers". I have no such knowledge of any mailout-lab's efficiency. The complete blood count and differential is one of the most basic of all laboratory tests, and at the Ann Arbor VAMC we do approximately 1,000 per month. Any VA laboratory is likely to have the technical ability to perform this test. As a Department, we are capable of establishing national tracking systems for particular veterans. For example, much of the work by the Special Committee in conjunction with Health Services Research and the Northeast Program Evaluation Center tracks individual patients with a PTSD diagnosis; and in Palo Alto, Health Services Research tracks care

of substance abuse patients. These programs are completely consistent with the type of registry requirements that are being stipulated with clozapine.

I would be very reticent to have this drug provided to needy veterans on my service essentially without the control by the physicians on my service. There may be times where the blood test (complete blood count) alone may be normal, but other things are going wrong with a patient. Thus, prescribing is not done by case managers or computers, and this is why medical school, residency, and years of experience are essential for professionals who treat medical illnesses, and especially, complex illness in a very complex patient. I would strongly support assistance from Congress in making this drug safely available for veteran patients.

I think that it is also important to point out for veteran and non-veteran patients, the public health issue. Schizophrenia, particularly chronic, treatment-resistant schizophrenia, is an illness that often completely robs a patient and the patient's family of their resources. It is a devastating, chronic condition. We still have many men in our outpatient programs, and in our long-term psychiatric units, who had their first psychotic episode when they were 18 and enlisted for World War II. Therefore, it is important to recognize that the very concept of a pharmaceutical and a managed pharmaceutical delivery system at a cost of $9,000 per year will, for many of these patients, exclude them from the possibility of effective, practical treatment. This will certainly be the case within Psychiatry Services of the Department of Veterans Affairs that are at best, marginally funded now.

Thank you for the opportunity to comment on these important topics.

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Testimony

of

Dr. David P. Niles, LPC, NCC, CCMHC, CMP (ABMP)

on behalf of the

American Association for Counseling and Development

Before the

U.S. House of Representatives

Subcommittee on Hospitals and Health Care,
Committee on Veterans' Affairs

June 28, 1990

Washington, D.C.

33-896 98

American Association for Counseling and Development is Committed to Equal Opportunity.

Good morning. Mr. Chairman and Members of the House of Representatives of the Veterans' Affairs Subcommittee on Hospitals and Health Care, my name is Dr. David Niles. I am a clinical mental health counselor and Chairman of the Post-Traumatic Stress Disorder Network for the American Mental Health Counselors Association, a division of the American Association for Counseling and Development. I also serve as the Deputy Chairman for the PTSD and Substance Abuse Committee of the Vietnam Veterans of America, Inc. I am a Vietnam veteran who served two tours of duty in Vietnam as an infantry platoon leader and infantry company commander. Today I speak to you on behalf of the American Association for Counseling and Development (AACD) and the American Mental Health Counselors Association (AMHCA).

AACD is a 56,000 member association representing professional counselors in a variety of settings including hospitals, community mental health centers, rehabilitation facilities, schools and universities, and private practice. My primary affiliation is with AACD's division of mental health counseling the American Mental Health Counselors Association, which represents over 12,000 professional mental health counselors.

Mr. Chairman, I thank you for the opportunity to address the committee with our views on H.R. 3037, providing for the expansion of services the Department of Veterans Affairs provides to veterans suffering from post-traumatic stress disorder (PTSD).

H.R. 3037 is an important and much needed piece of legislation. I commend you for your efforts to expand the services of the Department of Veterans Affairs to help veterans suffering from PTSD. As this bill accurately points out in Sec 2. FINDINGS, over 800,000 Vietnam-era veterans are currently suffering from PTSD. This equates to one-third of the veterans having served in Vietnam. However, only 10 percent of these Vietnam veterans suffering from PTSD have used the programs offered by the Department of Veterans Affairs for the treatment of PTSD. I'd like to talk with you briefly about the reasons for the low utilization rate, and in some instances will discuss how H.R. 3037 might be modified to improve utilization by individuals with PTSD. These reasons fall into 3 major categories:

1. Clinical diagnosis of PTSD
2. Access to services
3. Recruitment of qualified PTSD professionals and para-professionals

Fundamentally, Vietnam veterans, along with other victims of trauma, do not want to be diagnosed as mentally ill or suffering from a personality disorder. From the true mental health perspective, PTSD is a normal reaction by human beings to abnormal life experiences and/or events. PTSD is not a mental illness or personality disorder. This concept receives

dramatic support in the recent Twin Study of 715 monozygotic twin pairs in which one twin served in Vietnam while the other did not. There is a ninefold increase in the prevalence of PTSD comparing twins who experienced high levels of combat with their co-twin who did not serve in South East Asia. The key implication of this study is that PTSD is related to traumatic stressful life experiences and is not a result of characteriogical/personality disorders or bad parenting. PTSD is the result of the traumatic violence experienced in combat while in Vietnam.

The fact that PTSD is not a mental illness or personality disorder is further demonstrated in a study I conducted of 244 active duty Colonels and Lieutenant Colonels serving on the Department of the Army staff. This study conducted under the auspices of the George Washington University where I am an adjunct professor, finds an 18% alcohol abuse rate and a 20% PTSD level among these active duty officers. However, upon further analysis of the data as they relate to denial of problems by these active duty officer Vietnam veterans, the actual levels of alcohol abuse and PTSD levels are nearer to 33-35%. This equates to a third of the sample and is closely associated with the findings of other studies; specifically, that one-third of the Vietnam veterans are suffering from PTSD. Furthermore, the findings of this study clearly show a strong, statistically significant correlation between the levels of PTSD and alcohol abuse. This is also found in the emerging evidence of research literature relating to PTSD.

These findings should not be surprising to anyone. Why should the veterans on active duty, or serving in our reserve forces, be any different from those veterans who are no longer actively serving in our national defense? The key implication is that these active duty veterans avoid seeking help because of the stigma associated with PTSD; specifically, that it is a mental illness or personality disorder. I can assure you as a retired, infantry, Army Lieutenant Colonel and practicing clinical mental health counselor, that many of my colleagues are in fact having problems associated with PTSD and alcohol. The history of the Diagnostic and Statistical Manual (DSM) clearly demonstrates that the clinical professions have had a hard time justifying the inclusion of PTSD. Specifically, in 1952 PTSD was included in the DSM under the title "war neurosis". In 1968, is was deleted by the psychiatric community because they felt the veteran was suffering from "compensation neurosis." PTSD was re-introduced to DSM-III with one of the diagnostic criteria of "survivor guilt". Survivor guilt was then deleted from DSM-III-R (1987) for reasons that are not clear. DSM-III-R is now under revision with the special interests at work to define PTSD. Even neuroscientists do not have a clear understanding at this point as to what causes PTSD. There are no medications clearly designed

to treat PTSD. Medications do exist to treat certain symptoms. For example, tegretol may be used to control the veteran's explosive outbursts, however, it does not treat the underlying causes of the problem - PTSD. The primary approach in treating this problem is education and the encouragement of the expression of healthy feelings towards others, not through further numbing of emotions by drugs.

In order to ensure the increased availability of and improved access to services as outlined in H. R. 3037, we offer the following suggested modification:

- To Section 4, **Funding for Contracts for the Provision of PTSD Treatment** we recommend that contracts be awarded to those private facilities which have staff specializing in the treatment of PTSD and to therapists who have specialized training in the treatment of PTSD. These contracts should be available to all mental health providers including but not necessarily limited to psychiatrists, psychologists, psychiatric nurses, and **clinical mental health counselors**.

In addition, we would recommend that this funding should also be available to paraprofessionals who have been appropriately trained and/or certified to provide PTSD peer counseling.

By expanding the contract services to include a broad range of specifically trained professionals and paraprofessionals, we believe that this would encourage many of the 90% who currently do not access the VA services to come into the system. By training appropriately qualified Vietnam Veterans as para-professionals , we will help to break down the Vets first barrier to treatment - mistrust. These paraprofessionals, working under the supervision of trained mental health professionals would expand outreach capabilities to those Vets who are mistrustful of the current provider system and therefore not accessing these services. As a matter of record, the American Mental Health Counselors Association and the Vietnam Veterans of America, Inc. are already working on joint preliminary proposals to incorporate such a networking system.

By ensuring that a broad based provision of mental health services is available, we also ensure that those family members and significant others affected by have equal access to mental health services. Fundamental to the successful treatment of victims suffering from post trauma reactions is a healthy supportive social system. This not only includes immediate significant others but also the world of work and ultimately society as a whole. To this end, it is imperative that programs be funded that increase the level of awareness throughout society of the deleterious impact of the Vietnam experience upon the veteran

This would include Employee Assistance Programs, Family Counseling Centers, and Veteran Outreach Centers.

In order to ensure the sufficient recruitment and training of mental health professionals working with victims of PTSD we offer the following recommendation to H.R. 3037:

- To Section 5, **Use of Scholarship and Tuition Reimbursement Programs for Mental Health Professionals** we recommend expansion of the Health Professionals Educational Assistance Program to include but not be limited to **clinical mental health counselors**. This expansion would ensure an adequate supply of mental health professionals working with victims of PTSD. It is imperative that a broad based educational approach to the treatment of Veterans be initiated to help those who clearly do not need specific clinical interventions as their primary focus of treatment. As indicated, only 10% of those exhibiting PTSD are in need of intensive inpatient PTSD treatments. This provision, if expanded, would provide scholarship and tuition reimbursement programs for mental health professionals who would focus on the non-clinical as well as clinical treatment programs.

Mr. Montgomery, and members of the sub committee, I have summarized for you what AACD views as the critical areas to address with regards to H.R. 3037. By re-considering the clinical diagnosis of PTSD, the improved access to PTSD services for Veterans and their significant others, and the expansion of the scholarship and tuition reimbursement programs for mental health professionals, we are confident that the intent of H.R. 3037 will be fully realized.

I thank you for the opportunity to testify today.

STATEMENT OF

ROBERT D. MANHAN, SPECIAL ASSISTANT
NATIONAL LEGISLATIVE SERVICE
VETERANS OF FOREIGN WARS OF THE UNITED STATES

BEFORE THE

SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES HOUSE OF REPRESENTATIVES

WITH RESPECT TO

EXPANDING SERVICES TO VETERANS SUFFERING FROM POST TRAUMATIC STRESS DISORDER (PTSD)

WASHINGTON, D. C. JUNE 28, 1990

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE:

On behalf of the 2.8 million members of the Veterans of Foreign Wars of the United States (VFW) and its Ladies Auxiliary, I thank you for inviting us to participate in this hearing. We believe efforts to expand Department of Veterans Affairs (VA) services to veterans suffering from PTSD is a particularly important subject.

The VFW Field Representatives who are part of our national service staff visit various VA medical facilities throughout the country on a reoccurring basis. Generally speaking our staff has found there is a much greater demand for PTSD care from veterans than there are medical facilities or programs presently available to provide such treatment. Specifically, in some instances, there is a waiting period of up to one year before a PTSD applicant can enter an in-patient program. Interviews with veterans who have received this VA care were almost unanimous in stating their praise for the quality of service received. However, most also said their length of stay was too brief.

Our position on the Vet Center PTSD treatment efforts is more circumspect. While the VFW strongly supports readjustment counseling, we would prefer to eventually see the entire PTSD counseling program become a VA in-house effort. However, given the above facts and circumstances, we do support present efforts to reach veterans who seek assistance from Vet Centers, particularly where no other PTSD service facilities are available.

Bill H.R. 3037 offered by Congressman Jim Jontz of Indiana is strongly supported by the VFW. We know this bill presently has 115 cosponsor, to include over one half of all the members of the Veterans' Affairs Committee. In fact H.R. 3037 clearly answers VFW Resolution No. 693, "Expand PTSD Treatment Program." A copy of the resolution is attached to this statement.

What the Bill Will Do.

H.R. 3037 would add a minimum of 30 additional inpatient PTSD units to VA medical centers by 1994. This would provide about one VA inpatient PTSD unit per state. It would also add another 40 outpatient Vet Centers for readjustment counseling by 1994. The bill too provides stable funding for VA contract counseling programs for PTSD, which serve veterans in rural areas and other places not served by present VA facilities.

In addition to expanding PTSD treatment, H.R. 3037 would encourage VA to recruit qualified professionals to administer PTSD care by including psychiatrists, psychologists and others who specialize in the treatment of PTSD in the Health Professional Scholarship Program.

This bill would give permanent statutory authority to the Advisory Committee on Readjustment of Veterans. This is to advise and report on all activities relating to PTSD.

H.R. 3037 would also create a research program for the treatment of PTSD within the VA. It would study the best treatment methods for PTSD to ensure that quality care is given on a consistent basis throughout the country.

Last, H.R. 3037 would establish a pilot program for PTSD care in halfway houses. This would take an additional burden from the already overcrowded VA medical system.

Why the VFW Supports H.R. 3037

In 1988 the Research Triangle Institute (RTI) under contract from VA completed a study on the readjustment of Vietnam veterans. This study concluded that as many as 15 percent of Vietnam theater veterans are presently suffering from PTSD and another 11 percent have some PTSD symptoms. This means about 800,000 veterans of the 3.1 million who served in Vietnam need PTSD service. This is a 300,000 greater number of affected veterans than previously estimated.

The National Vietnam Veterans Readjustment Study dealing with the readjustment problems of Vietnam veterans was initiated in 1984. The results of this landmark, VA-funded effort was released in December 1988 and concluded that approximately 100,000 veterans had sought PTSD treatment from VA. This means only about 12 percent of the new recognized total of those who suffer, in varying degrees from PTSD and/or PTSD symptoms, have ever been seen by VA.

Also, because the PTSD symptoms of hyperalertness, anxiety, and irritability are often chronic and recurrent, characterized with periods of improvement or worsening of symptoms, a greater continuum of care is needed to match the varying needs of veterans who experience PTSD problems.

Based on these factors we believe H.R. 3037 is a major effort to expand on VA's existing array of treatment sites and services to help many more veterans gain mastery over their PTSD symptoms and to share more fully an improved, if not perfect, social and occupational life style.

As stated previously, H.R. 3037 would provide for 40 additional Vet Centers by the year 1994. The VFW would point out that the Vet Center program is temporary by law and we suggest that rather than expand the program by the specific number contained in H.R. 3037, the bill be amended to allow the addition of Vet Centers only where the need is warranted.

Clozapine

The subcommittee is also interested in receiving testimony regarding the new prescription drug clozapine (cloz-a-peen). It is used exclusively for treating the mental disorder of schizophrenia. We also know this drug is manufactured and distributed by Sandoz Pharmaceutical Company. Further, we know that clozapine cannot be used in some instances because a patient can suffer from the lethal side effect of having his white blood cells destroyed.

But more to the point for the purpose of this hearing is the new and unique manner clozapine is being marketed. Specifically, the drug and a "close monitoring program" are being sold as a package to VA. Unfortunately this package concept increases the price to the point where it costs about nine thousand dollars per year, per patient, to be treated with clozapine. This is a significant sum of money when we recall the fact VA is presently treating some 27,000 schizophrenic patients annually. Assuming only one-third this total could be treated with clozapine, it would still cost about $81 million each year at the present price just to use clozapine for about 9,000 veterans.

The VFW always supports and appreciates any and all new products and technologies the greater scientific and medical communities makes available to mankind. We also strongly support the VA's continuous efforts to provide the best possible medical treatment in a cost-effective manner. Accordingly, we believe some reasonable agreement can be worked out between the VA medical staff and Sandoz Company that would allow VA to prescribe the medication, conduct the important and expensive follow-on laboratory work as well as patient interviews to preclude any veteran from becoming a victim of the previously mentioned lethal side effects. We recognize the importance of this "close monitoring program" simply because we also realize that most schizophrenic veterans also suffer from other medical diseases which very much complicates the treatment process. In our judgment this approach would reduce the per unit cost of clozapine to the government while ensuring a fair return on their investment to the pharmacectical company and at the same time ensuring the highest professional standards of medical treatment to our veterans.

This concludes the VFW statement. I am prepared to answer any questions at this time. Thank you Mr. Chairman.

Resolution No. 693

EXPAND PTSD TREATMENT PROGRAM

WHEREAS, Post Traumatic Stress Disorder (PTSD) is a recognized residual of military combat experience; and

WHEREAS, the Department of Veterans Affairs has established the treatment of this condition as one of its top priorities; and

WHEREAS, sixteen Department of Veterans Affairs medical centers have already established Post Traumatic Stress Disorder Treatment Units, although such units have been hampered by limited funds; and

WHEREAS, there are plans to establish additional PTSD treatment programs through the Medical District Initiated Planning Process as well as other programs which are being developed for outpatient treatment; and

WHEREAS, it is essential that these additional specialized treatment units be created in each suitable medical center to assure the availability of care in all regions of the VA system; now, therefore

BE IT RESOLVED, by the 90th National Convention of the Veterans of Foreign Wars of the United States, that while recognizing the vast improvements made in treatment of Post Traumatic Stress Disorder by the Department of Veterans Affairs, we strongly support legislative or other initiatives to increase funding specifically earmarked for the establishment of specialized inpatient Post Traumatic Stress Disorder Treatment Units at all suitable VA medical centers.

Adopted by the 90th National Convention of the Veterans of Foreign Wars of the United States, held in Las Vegas, Nevada, August 18-25, 1989.

Resolution No. 693

STATEMENT OF FRANK C. BUXTON, DEPUTY DIRECTOR
NATIONAL VETERANS AFFAIRS AND REHABILITATION COMMISSION
THE AMERICAN LEGION
BEFORE THE SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE
COMMITTEE ON VETERANS AFFAIRS
UNITED STATES HOUSE OF REPRESENTATIVES
JUNE 28, 1990

Mr. Chairman and Members of the Subcommittee:

The American Legion appreciates this opportunity to express its views on the provision of mental health care services to veterans suffering from Post-Traumatic Stress Disorder (PTSD) and H.R. 3037.

The subject of Post-Traumatic Stress Disorder, and the manner in which it is approached by VA is an issue that is extremely important to The American Legion. In the early 1980's when it appeared that the government's efforts to study Vietnam veterans physical and mental health problems stalled, The American Legion joined with two eminent researchers, Drs. Jeanne and Steven Stellman, to undertake a scientific study of Vietnam veterans who were members of The American Legion. The findings of the epidemiologic study highlighted a variety of factors, including the relationship between varying levels of combat and PTSD, and health effects related to exposure to Agent Orange, which have deeply affected the post-service adjustment and health status of these Vietnam veterans. The results were published in the December 1988 issue of the scientific journal Environmental Research. As highlighted by the recent findings of both The American Legion/Columbia University Study and VA's Vietnam Veterans Readjustment Study, conducted by the Research Triangle Institute (RTI), Vietnam combat veterans in particular continue to suffer a variety of health and readjustment problems most notably those related to PTSD. Other veterans of the Vietnam Era also have problems related to readjustment, employment, medical care, and homelessness.

The RTI study, released in December 1988, reveals that approximately 15 percent or 450,000 Vietnam combat veterans meet full clinical PTSD criteria and another 11 percent meet some, but not all, the clinical symptoms of PTSD, as defined by DSM-IIIR.

The findings of The American Legion/Columbia University Study shows that as the combat intensity of the Vietnam veterans increased, so did the rate of suffering from PTSD. Fifteen percent of the study group who served in Southeast Asia who had experienced high combat fulfilled the medical criteria for PTSD.

The study also shows that the problem does not diminish with time. Although some of the veterans suffered their trauma as much as 20 years ago, the same level of PTSD symptoms persist. By correlating PTSD with other psychological measures used in the study, the researchers were able to conclude that a veteran with PTSD may also be

suffering from depression, anxiety and other psychological problems.

Mr. Chairman, with respect to H.R. 3037, this measure would provide for the expansion of the services the Department of Veterans Affairs (VA) provides to veterans suffering from post-traumatic stress disorder, and for other purposes.

Section 2 of the bill sets forth the following Congressional findings:

(1) over 800,000 Vietnam - era veterans suffer from post-traumatic stress disorder (PTSD).

(2) only 10 percent of Vietnam - era veterans suffering from PTSD have used the programs offered by the Department of Veterans Affairs for the treatment of PTSD.

(3) expanding the vet center program, inpatient PTSD treatment, and other PTSD treatment programs would be effective methods of serving more veterans suffering from PTSD.

(4) providing constant funding for the Readjustment Counseling Program of the Department of Veterans Affairs would be beneficial in treating veterans suffering from PTSD.

(5) coordinating and developing a standard PTSD treatment program would greatly enhance the Department of Veterans Affairs' ability to more effectively treat and rehabilitate veterans suffering from PTSD.

Section 3 provides that the Secretary of Veterans Affairs shall increase the number of existing Veterans Outreach Centers by not less than 20 additional units by December 31, 1991, and by not less than an additional 20 units by December 31, 1994. These centers are to be established in cities that do not currently have Veterans Outreach Centers.

This section further provides that the Secretary shall increase the number of existing inpatient post-traumatic stress disorder treatment facilities by not less than 15 additional units by December 31, 1991, and by not less than an additional 15 units by December 31, 1994.

Mr. Chairman, the Vet Center program has become an integral part of the overall VA health care delivery system, enhancing continuity of care and greatly improving the understanding of the psychological readjustment needs of combat veterans throughout VA.

The nationwide workload totals for the Readjustment Counseling program in FY 1989 showed a steady increase for new veteran clients, and the highest number of total visits since the inception of program in FY 1980. Available figures show that last year

80,871 new veteran clients were seen, and there was a total of 116,667 veterans seen during 521,934 visits. Cumulatively, from FY 1980 thru FY 1989, 641,355 veterans have been seen, resulting in 3.7 million veteran visits.

Collectively, there are 196 full service and satellite Vet Centers currently in operation. The spectrum of services provided by Vet Centers, and Post-Traumatic Stress Disorder programs, both inpatient and outpatient, provide a good mix of treatment modalities to address the social and psychological problems of Vietnam veterans. In our view, an enhancement in the quantity of programs and services would better serve the needs of this client group.

The American Legion believes that additional Veterans Outreach Centers are needed in currently underserved areas, and staffing at some current Centers needs to be augmented. Given sufficient resources the expansion of the program is highly desirable. A mechanism needs to be established to determine the number, size and location of new Centers which are required. Generally, a reasonable demographic gauge is to determine how many Vietnam veterans reside within a 50-mile radius of a proposed new Center. Also, an additional measurement is to calculate the proximity of a proposed Center to other VA facilities which may be able to provide similar health care services.

Based on the conclusive findings of a demographic analysis and needs assessment, The American Legion supports a modest expansion of the Veterans Outreach Program at strategic locations. We also see no reason why entitlement to services provided through Veterans Outreach Centers should not be extended to World War II and Korean Conflict veterans, and veterans who have served in hostilities after May 7, 1975, as we have previously mentioned in testimony over the past several years.

Mr. Chairman, in relation to the second provision of section 3, veterans suffering from Post-Traumatic Stress Disorder are provided treatment through a multitude of different programs, depending upon the VA facility from which the individual seeks treatment. It appears that in a majority of the medical centers, veterans with PTSD are treated on general psychiatry wards. Some are treated on an outpatient basis through the mental health clinic or various other programs. There is a lack of consistency throughout the VA medical care system.

There are 16 Specialized Inpatient PTSD Units (SIPUs) at VA medical centers around the country that carry out programs of treatment for veterans with critical cases of PTSD. Another four inpatient units are planned to be activated by the end of FY 1990. At last count, the existing and planned operating bed total for all SIPUs is

approximately 450 beds.

In addition to the SIPUs, VA recently activated 23 specialized clinical teams based at VA medical centers throughout the country to provide outpatient treatment to veterans with PTSD. An additional 21 PTSD clinical teams are planned to be activated over the next two years. As we understand it, the decision to activate the additional SIPUs and the outpatient clinical teams followed the recommendations of the VA's Special Committee on PTSD, based in part on the results of the Research Triangle Institute study.

The American Legion believes VA must develop an ongoing coherent strategic plan to provide treatment to those veterans suffering from PTSD. A full continuum of care must be made available to match the veterans' severity of illness. An expansion of inpatient treatment units would certainly serve to reduce long admission waiting lists and provide better demographic access to care.

Mr. Chairman, The American Legion is mandated by Resolution No. 10 adopted by its National Executive Committee in May 1989, to urge Congress and the Administration to provide adequate funding for the continued operation of the PTSD inpatient treatment program and for the badly needed expansion of the program. As commented on with regard to the proposed expansion of Veterans Outreach Centers, we believe a thorough demographic analysis and needs assessment must be accomplished to determine the number, size and location of proposed new PTSD inpatient treatment programs. We are also mindful that new resources would be required to accomplish an expansion of both of these programs.

Section 4 of the measure would require the Secretary of Veterans Affairs to allocate $10 million of the amount available to the Secretary in fiscal year 1990 for the provision of services to veterans for the treatment of PTSD for contracts with private facilities and therapists in accordance with section 612A(e) of title 38, United States Code.

Mr. Chairman, according to available information, the Readjustment Counseling Service has $5 million in fiscal year 1990 for the provision of contract services with private facilities and therapists for PTSD care. In order to provide $10 million for this function in fiscal year 1990, new resources would be required. The American Legion agrees with the spirit of the measure, and we must point out that funds for PTSD contract services as administered by the Readjustment Counseling Service have been decreased from $8 million just a few years ago to the present $5 million level.

In our view, it would be a disservice to Vietnam veterans to build-up this program through the remainder of fiscal year 1990 and then discontinue services. If new funding to support this provision was not made available, money would have to be diverted from the Veterans Outreach Center program. We would support increasing the amount of funding available for PTSD contract care in future year budgets but cannot support reducing the amount of funding available for Veterans Outreach Centers to accomplish this goal. In the view of The American Legion it is more cost-effective to provide counseling and related services to veterans in Outreach Centers and VA treatment facilities, and by modestly expanding these programs less funding would be required for contract care.

Section 5 would provide for the Secretary of Veterans Affairs, in administering the Health Professionals Educational Assistance Program (chapter 76 of title 38, United States Code), to encourage the participation of individuals in the program who desire to become psychiatrists, psychologists, and psychiatric nurses specializing in the treatment of PTSD. In addition, the Secretary shall consider designating, pursuant to section 4312(b)(3) of title 38, United States Code, additional fields of education or training that may be beneficial for the comprehensive treatment of veterans suffering from PTSD.

Mr. Chairman, The American Legion believes that the proposal to provide education and training opportunities to increase the number of health professionals involved in the care and treatment of veterans suffering from PTSD, and to enhance the skills of individuals already contributing in this endeavor, deserves the fullest support of this Committee.

The purpose of the Educational Assistance Program is to assist in providing an adequate supply of trained health-care personnel for the VA and the Nation. In order to ensure that the supply of academically trained personnel in the provision of PTSD care and treatment is sufficient, this proposal is fully supported by The American Legion.

Section 6 of the measure would amend Subchapter II of chapter 3 of title 38, United States Code, by adding a new subsection which would mandate the establishment of an Advisory Committee on Readjustment of Veterans.

This proposal provides that the Committee shall be appointed by the Secretary from the general public and shall include individuals who are recognized authorities in fields pertinent to the social, psychological, economic, or educational readjustment of veterans, who are not current employees of VA, and who have preferably been awarded a campaign or expeditionary medal from the Armed Forces.

Under this proposal the Secretary shall appoint and the Committee shall include as ex-officio members, five individuals from various Federal departments and agencies, and at least five members of veterans service organizations chartered by an Act of Congress, but no more than one member from the same organization. The Secretary may also invite other representatives of departments and agencies of the United States to participate in the meetings and other activities of the Committee. The term of service of any member may not exceed three years and the Secretary shall determine the number of members, except that such number may not exceed 20 nor be less than 12.

The measure provides that not later than July 1 of each year, the Committee shall submit to the Secretary a report on the programs and activities of the VA that pertain to the social, economic, educational, and psychological readjustment of veterans. The Secretary shall submit a summary of all reports and recommendations of the Committee to the Congress with each annual report.

Mr. Chairman, The American Legion, in general, supports the intent of this measure. However, we must point out the proposal would significantly alter the nature of the Secretary's administratively established Advisory Committee on the Readjustment of Vietnam Veterans, which is, in the main, consumer oriented. The proposal, we believe, provides for too many federal employees as ex-officio members of the Committee.

Currently, the Secretary's Advisory Committee on the Readjustment of Vietnam Veterans plays an important role with regard to VA policy considerations. The Committee is hardworking and helpful and productive in guiding VA policy in the social and psychological readjustment of Vietnam combat veterans. Since the Secretary's Advisory Committee is focused toward the readjustment of combat veterans, The American Legion strongly believes the proposal to statutorily establish the Committee should also focus on the readjustment problems of combat veterans of all wars or conflicts. We also recommend that the make-up of the proposed statutorily empowered Advisory Committee be the same as the current Advisory Committee.

Section 7 of this proposal would amend Subchapter II of chapter 17 of title 38, United States Code, to establish a pilot program for PTSD care in halfway houses. This program would be similar to the halfway house program for drug and alcohol abuse treatment and would authorize the Secretary to contract for care and treatment of veterans suffering from PTSD in halfway houses, therapeutic communities, psychiatric residential treatment facilities, and other community-based treatment facilities.

This proposal directs the Secretary, in consultation with the Secretary of Labor and

the Director of the Office of Personnel Management to urge all Federal agencies and appropriate private and public firms, organizations, agencies and persons to provide appropriate employment and training opportunities for veterans who have been provided treatment and rehabilitative services for PTSD and have been determined to be sufficiently rehabilitated.

The proposal also directs the Secretary of Veterans Affairs to provide veterans suffering from PTSD who otherwise are not eligible for VA treatment and services, assistance in obtaining treatment and rehabilitative services from sources outside VA, and to advise such individuals of their rights to apply to the appropriate military discharge review board for review of such individual's discharge record.

The proposal authorizes the Secretary to provide care and treatment to any person in the active military, naval, or air service who is determined to have post-traumatic stress disorder during the last thirty days of such member's enlistment period or tour of duty. The transfer of any such member of the Armed Forces shall be made pursuant to such terms as may be agreed upon by the Secretary concerned and the Secretary of Veterans Affairs, subject to the provisions of the Act of March 4, 1915 (31 USC 686).

The proposed pilot program shall be authorized for five years following the fiscal year of enactment and the Secretary shall report to the Congressional Committees on Veterans' Affairs, not later than March 31, 1993, the findings and recommendations of the Secretary pertaining to the operation of the pilot program through September 30, 1992.

Mr. Chairman, VA currently operates several aftercare programs for veterans who have received PTSD inpatient care. The Veterans Outreach Center program, individual VA medical center outpatient care, and the clinical outreach team program all focus on providing a supportive environment to patients who have been treated by VA for post-traumatic stress disorder. Within these programs are health-care professionals who are trained and experienced in the treatment of PTSD. VA has developed some innovative PTSD aftercare programs which are domiciliary based, providing an intermediate level of care, with community-based treatment components.

The recognition of a need for follow-up PTSD care and treatment is important and in the view of The American Legion, due to the limited amount of expertise available to treat PTSD in community halfway houses or residential treatment facilities, a well developed and closely monitored program would be required. There are many veterans who no doubt would benefit by having access to community-based services for PTSD

aftercare, however, the effectiveness of such a program would depend on ensuring the proper level of care can in fact be provided.

Mr. Chairman, under current VA/DOD sharing agreements (Public Law 97-174), active duty military personnel are authorized to be treated for certain conditions in VA medical facilities. So long as a stigma of having received psychiatric treatment will not adversely affect an individual's enlistment period, tour of duty, or reenlistment potential, and will not adversely reflect on an individual in any manner, The American Legion has no objection to the proposal of VA furnishing PTSD treatment to active duty military personnel as set forth in the measure. We have supported the provision of counseling to active duty personnel in Vet Centers in the past.

Section 8 of the bill would require the Chief Medical Director to conduct a research program relating to the treatment of PTSD, through the National Center on Post-Traumatic Stress Disorder. The purpose of the program is to determine the most effective modalities of treatment for PTSD in both inpatient and outpatient settings and to coordinate and standardize the treatment of PTSD in VA facilities treating veterans suffering from PTSD.

Mr. Chairman, since the establishment of PTSD treatment programs in VA, a body of knowledge has been developed with regard to the most effective treatment modalities for PTSD. The American Legion recognizes that staffing patterns at various VA inpatient PTSD treatment units are not identical, and that different centers have focused on various treatment regimes, such as long inpatient lengths-of-stay with little community interaction, while other units have focused more on community-based treatment. VA has been conducting studies on what clinical approach works best for the treatment of PTSD, based on empirical and practical experience. The VA Mental Health and Behavioral Science Service plans to publish a program guide manual this year on the care and treatment of veterans suffering from PTSD. Although The American Legion has no specific objection to the proposal to require VA to conduct a research program relating to the treatment of PTSD, we feel the recent reorganization of the National Center on Post-Traumatic Stress Disorder was undertaken with this purpose in mind.

Mr. Chairman, there are two remaining issues relative to PTSD which we believe deserve comment.

First, is the persistent problem in the manner in which PTSD claims are handled by VA. There are still adjudicators who are hesitant to grant service-connected disability compensation to veterans with PTSD, regardless of the amount of evidence on record or

the extent to which the claims have been developed. It is our judgment that too many valid claims are still being denied by VA regional offices, and then subsequently by the Board of Veterans Appeals.

One of the recurrent problems with respect to these cases, is the fact that many times the VA psychiatric examination reports do not contain adequate military histories. Many times no attention whatsoever is given to the veteran's military duties and combat or other life-threatening situations.

In the opinion of The American Legion, although there has been some improvement in recent years, additional emphasis and training is needed in both the examination process and the adjudication of claims for PTSD in a number of field stations.

Closely related to this issue is the fact that many veterans are diagnosed by VA physicians as meeting all six clinical criteria for PTSD, but failing to receive a service-connected disability rating, are not considered as Category A veterans, and they are denied priority treatment in VA medical facilities. Without receiving a disability rating for diagnosed PTSD, discretionary care veterans (nonservice-connected Category A-B-C) are subject to receiving VA treatment on a space and resource available basis. With the budgetary shortfall reported throughout the VA medical care system, there is a distinct possibility that veterans suffering from PTSD could be turned away from receiving care due to means test criteria. In our view, VA has an obligation to help these veterans.

Mr. Chairman, that concludes our statement.

PARALYZED VETERANS
OF AMERICA
Chartered by the Congress
of the United States

STATEMENT OF
JOHN C. BOLLINGER, ASSOCIATE LEGISLATIVE DIRECTOR
PARALYZED VETERANS OF AMERICA
BEFORE THE
SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE
OF THE
HOUSE COMMITTEE ON VETERANS' AFFAIRS
CONCERNING
VA MENTAL HEALTH CARE SERVICES
AND
H.R. 3037, THE "VETERANS PTSD TREATMENT AND PSYCHOLOGICAL
READJUSTMENT ACT OF 1989"
JUNE 28, 1990

Mr. Chairman and Members of the Subcommittee, Paralyzed Veterans of America (PVA) is grateful for the opportunity to appear before you today to express our concerns and opinions regarding the Department of Veterans Affairs' (DVA) ability to care for veterans suffering from Post-Traumatic Stress Disorder. We also appreciate this opportunity to comment on H.R. 3037, legislation sponsored by the Honorable Jim Jontz, which would provide for the expansion of services which the Department provides to veterans suffering from Post-Traumatic Stress Disorder (PTSD).

Post-Traumatic Stress Disorder (PTSD) was not identified and recognized as a disorder until 1980, although its symptoms had been prevalent in various military personnel for many years. Prior to 1980, PTSD was referred to as "combat fatigue," or "delayed stress." However, by 1980, an ever growing body of research on the effects of psychic trauma had accumulated to the point where many practitioners began to recognize post-traumatic stress syndromes as the normal consequence of abnormally stressful events.

PTSD is a chronic, psychological disorder which can affect an individual's ability to participate in life. In 1980, the American Psychiatric Association first acknowledged Post-Traumatic Stress Disorder as "a valid clinical entity which characterizes a well-defined syndrome of behavioral adaptation following profoundly stressful life-events."

In some individuals this disorder may be barely noticeable, while in others, the disorder may lead to total incapacitation. It is a disorder which, for some veterans, has lain dormant since the time of the traumatic event only to become apparent after another life crisis is experienced. For other veterans, it is a disorder which has haunted them on a daily basis since experiencing the traumatic event.

The most illustrative evidence of the pervasiveness of PTSD among combat veterans is contained in the National Vietnam Veterans Readjustment Study, conducted by the Research Triangle Institute (RTI). According to the final report, released in November 1988, 15.2 percent of male Vietnam theater veterans and 8.5 percent of their female counterpart are currently suffering from "full-blown" cases of PTSD. Another 11.1 percent of males and 7.8 percent of females, or a total of 350,000 theater veterans suffer from trauma-related symptoms which, due to the lack of intensity, are not characterized as "full-blown" PTSD cases.

Mr. Chairman, the Committee is familiar with the results of this and other studies concerning the psychological and social characteristics of Vietnam veterans. We all recognize that war places intense physical and psychological demands on those who participate. Some individuals can more readily cope and assimilate these experiences, while others develop traumatic wounds which, unless treated, will never heal. Through the efforts of DVA's readjustment counseling services - particularly the Vet Center program - VA has developed successful techniques for assisting veterans to live with PTSD and overcome this disability.

Authorized by Public Law 96-22, the first Vet Center opened its doors in 1980 to treat a problem that was claimed to be unique to Vietnam veterans. Subsequently, the knowledge and counseling techniques developed within the Vet Center program have led the VA, and the medical community at large, to recognize that adverse reactions to severe stress and traumatic incidents can have long-lasting effects on anyone, not just Vietnam veterans or combat veterans as a group. Counseling, particularly group counseling, techniques for individuals involved in major accidents or natural disasters appear now to be routine experiences. This is still a new science which gauges the psychological, even physical, long-term reactions to stress. Much more work needs to be done through research and clinical education. But the VA has clearly broken ground in this arena and should not miss any opportunity to capitalize on these accomplishments.

Today, PTSD is a disorder which has gained recognition in the medical field. Through efforts to advance research and treatment of PTSD, the VA has made great strides in meeting the needs of our veterans. These efforts have also greatly advanced the cause of mental health science in general, benefitting the Nation and all Americans.

PVA believes that PTSD is not a disorder inherent to Vietnam veterans. Research indicates that PTSD may affect any individual experiencing a single episode of severe stress. Therefore, PVA strongly believes that eligibility for readjustment counseling services should be broadened to allow access and treatment for veterans of all wars or designated armed conflicts. A veteran in need should not be denied access to available and appropriate VA services merely based on his or her period of military service.

H.R. 3037, the "Veterans PTSD Treatment and Psychological Readjustment Act of 1989"

As a result of the significant unmet needs which exist in VA's PTSD treatment program, PVA is pleased to support H.R. 3037, a bill which expands the services VA provides to veterans suffering from PTSD. We have several suggestions which we believe may improve the bill, however, we endorse the general concept and believe it will go a long way in addressing the numerous problems which face veterans suffering from PTSD.

We appreciate the deep concern which Representative Jim Jontz has demonstrated for the well-being of individuals who must rely on the mental health services of the Department of Veterans Affairs. Specifically, Mr. Jontz's dedication to a successful VA PTSD program will greatly benefit those veterans whose disabilities, although not dramatically visible, take a devastating toll on the daily lives of those men and women who live with the internal pain of mental illness. Mr. Jontz, PVA thanks you and the many co-sponsors of H.R. 3037 for recognizing the critical importance of a viable PTSD program which is able to reach all those eligible individuals who so desperately need such professional care.

Mr. Chairman, the statistics alone are overwhelming when one considers the vast numbers of veterans who currently suffer from PTSD. As stated in the November 1988 National Vietnam Veterans Readjustment Study (NVVRS), over 800,000 Vietnam veterans, both male and female, suffer the effects of PTSD in varying degrees. Further, since PTSD is thought to be chronic rather than acute, the lifetime prevalence of the disorder necessitates, in our opinion, the availability of VA professional help both now and in the foreseeable future.

Although we believe it will be many years before we see a decline in the number of veterans seeking help, we recognize that at some point down the road the need for an expanded PTSD program may very well ebb and the demand for PTSD care may diminish. We believe at that point, the community-based concept of the Vet Center program would provide an excellent foundation on which to base VA services and counseling for elderly and other disadvantaged veterans who currently slip through the cracks of an understaffed Veterans Assistance Service. We therefore see no merit in any effort to shrink the program or pull Vet Centers back into the mainstream of VA Medical Centers.

Prior to our comments on H.R. 3037, we wish to reiterate several long-standing PVA concerns about PTSD care. First, we firmly believe that such care should be offered to veterans of other wars whose need for professional care is as critical as that needed by veterans of Vietnam. Although many World War II veterans, Korean War veterans, and veterans from other conflicts have come to Vet Centers for help, they have been turned

away, or in some cases, treated illegally, because VA does not have the authority to administer professional PTSD care except in the case of Vietnam veterans. We believe the absence of authority to treat other combat veterans for PTSD leaves an enormous gap in what should be VA's moral obligation to provide care, on an equitable basis, for all PTSD sufferers. To do less is simply wrong. Further, we do not believe that such increased eligibility would add significant cost or workload to the Readjustment Counseling Program.

Second, we emphasize that PVA's desire to enact eligibility for all outpatient services and extended care for all Category A veterans includes the availability of professional care for those with PTSD. Although not specifically stated in the Independent Budget for FY 1991, it has certainly been, and continues to be, our intention to include such care in our quest to enact comprehensive health care for all Category A veterans.

Section 3 of H.R. 3037 proposes to increase the number of Vet Centers and in-patient PTSD treatment facilities to accommodate the ever-growing number of veterans seeking professional care. With the number of new patients per year exceeding 80,000, we do not see how expansion can be avoided. There is simply too much at stake in terms of the relationships between PTSD and drug abuse, incarceration, other psychiatric disorders, family problems, and a host of other potentially adverse readjustment complications. The unmet need has clearly been shown to exist. Like other service-connected physical disabilities, VA must provide quality treatment for all those with PTSD.

Regarding the actual number of additional Vet Centers called for in H.R. 3037, we believe an increase of forty centers by 1994 should be sufficient to address the growing demand for care. If necessary, the legislation allows for additional centers beyond the mandated forty. We endorse this provision.

Section 3 of the bill also states that the Secretary shall establish the new Vet Centers in cities that do not currently have such centers. In most cases, we believe that this provision will serve eligible veterans well. However, we believe that some flexibility should be given to the Secretary to improve or expand services in large urban areas that may need another Vet Center in addition to the PTSD services already provided. We also believe the interests of PTSD patients may be best served by expanding some existing centers in addition to the establishment of new centers.

Section 4 of the bill states that $10 million of the funds available to the Secretary in FY 1990 for PTSD care shall be allocated for contracts with private facilities and therapists. Although we understand the need - in certain cases - for such contracts, we believe this money could be used more wisely and efficiently if applied to the expansion and establishment of Vet Centers. It is more cost-effective, we believe, to open and staff a Vet Center, than to contract out services or treat patients on an in-patient basis. Further, if more funding is ultimately authorized for PTSD contract services, it must not be reprogrammed from existing program dollars. Funding for such contract services should be in the form of an additional appropriation.

PVA supports Sections 5, 6, 7, and 8 of the bill. Regarding the establishment of a new Advisory Committee on Readjustment of Veterans, we totally support the concept. However, we note that the Secretary may appoint as few as five members from veterans service organizations. We believe VSO's and "consumer advocates" should play a larger role in the function of the committee.

Regarding Section 7, we believe a pilot program for the contracting services for treatment and rehabilitation of PTSD patients is an acceptable short-term method by which we can measure the potential success of such an approach. In this case, the program would expire on September 30, 1992, at which time VA should have a better understanding of the merits of contracting such rehabilitation services. Since VA presently has only limited means by which to provide such rehabilitation to an ever-growing number of PTSD patients, we believe it is appropriate that experts in the community be involved to provide care in half-way houses, psychiatric residential treatment centers, and other community-based treatment facilities for eligible veterans suffering from PTSD.

Although we support Section 7 of the bill, we believe that, to every extent possible, VA's Vocational Rehabilitation Service should work hand-in-hand with VA hospital and Vet Center personnel in an effort to case-manage

individual rehabilitation programs for PTSD patients. We continue to believe the Veterans Benefits Administration/Veterans Health Services and Research Administration relationship represents a weak link in disabled veterans' vocational rehabilitation which must not be allowed to persist. Treatment and rehabilitation of PTSD patients could be best performed by VA personnel if a coordinated case-management approach was implemented and sufficient funds were made available.

PTSD Funding

Mr Chairman, as you know, the President's budget request contained no increase in funding for PTSD treatment services for Vietnam veterans in spite of the findings disclosed in the NVVRS report - VA's own major PTSD study. Presently, VA's PTSD units have exceptionally long waiting lines and the distribution of specialized resources remains uneven.

We believe the Senate Committee on Veterans' Affairs' recommendation of $12.4 million in budget authority and $10.7 in outlays will go a long way in addressing some of the problems which plague the existing PTSD program. More recently, the House Subcommittee on Appropriations for VA, HUD, and Independent Agencies acknowledged the shortfalls in the PTSD program by reporting to the full Committee that extra funds should be allocated in this area.

The importance of the treatment and rehabilitation of those veterans with PTSD must not be underestimated. The problems are real and they continue to grow in number and, in many cases, severity. We must recognize that the government's investment in VA's mental health programs is as important as other physical disabilities. Adequate funding for quality health care, including an expanded PTSD program, is the right thing to do.

Mr. Chairman, that concludes my remarks. I will be happy to answer any questions you may have.

STATEMENT OF
DAVID W. GORMAN
ASSISTANT NATIONAL LEGISLATIVE DIRECTOR
FOR MEDICAL AFFAIRS
DISABLED AMERICAN VETERANS
BEFORE THE
SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE
OF THE
COMMITTEE ON VETERANS AFFAIRS
U.S. HOUSE OF REPRESENTATIVES
JUNE 28, 1990

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE:

On behalf of the more than 1.3 million members of the Disabled American Veterans and its Ladies' Auxiliary, may I say how very much we appreciate the opportunity to appear before the Subcommittee today to offer our views on the Department of Veterans Affairs' (VA) ability to provide treatment for Post Traumatic Stress Disorder (PTSD) and, specifically, H.R. 3037.

Mr. Chairman, it has been a little over 17 years since the evacuation of Saigon which signaled our nation's end of official activities in the Republic of Vietnam. Some 15 years have lapsed since the end of the Vietnam era was proclaimed by then President Gerald R. Ford -- May 7, 1975.

However, the debate of the nature and extent of our involvement in Vietnam has been an oft debated issue from nearly all quarters of the country. Perhaps the most commonly mentioned and troublesome area of such debate centers on the problems and challenges faced by Vietnam era veterans in readjusting to civilian life.

Mr. Chairman, the DAV has continually expressed its commitment and concern toward assisting Vietnam era veterans suffering psychological problems associated with their military service in Vietnam. It was the DAV that provided funds for "The Forgotten Warrior Project," which led in October 1978, to the DAV initiating our own Vietnam Veterans Outreach Program. The results of this study had a direct influence on not only our organization's establishment of a specific counseling program for Vietnam veterans but, we feel, on the decision of Congress to provide the necessary funds which authorized the Veterans Administration to create "Operation Outreach" and subsequently establishing the current network of Vet Centers (Public Law 96-22).

Mr. Chairman, in 1983 Congress directed the VA (Public Law 98-160) to conduct a comprehensive study of the prevalence and incidence in the population of Vietnam veterans of PTSD and other psychological problems in readjusting to civilian life. In September 1984, the VA awarded a contract to the Research Triangle Institute (RTI) to conduct the mandated study, which has become known as the National Vietnam Veterans Readjustment Study (NVVRS).

On November 7, 1988, the NVVRS was completed and released. Highlights of the findings include:

* Conducted in response to Public Law 98-160, the National Vietnam Veterans Readjustment Study (NVVRS) is the most rigorous and comprehensive study to date of the prevalence of PTSD and other psychological problems in readjusting to civilian life among Vietnam veterans.

* The sample of veterans examined in the NVVRS was broader and more inclusive than those of past

studies. As a result, the descriptions of Vietnam theater and era veterans found in the report are in some ways different from, but more representative than, descriptions provided in previous research.

* The majority of Vietnam theater veterans have made a successful re-entry to civilian life and currently experience few symptoms of PTSD or other readjustment problems.

* Although in general, male Vietnam theater veterans do not differ greatly in their current life adjustment from their era veteran counterparts, there is some evidence that female theater veterans currently experience more readjustment problems than Vietnam era veteran women of similar age and military occupation.

* NVVRS findings indicate that 15.2 percent of all male Vietnam theater veterans are current cases of PTSD. This represents about 479,000 of the estimated 3.14 million men who served in the Vietnam theater. Among Vietnam theater veteran women, current PTSD prevalence is estimated to be 8.5 percent of the approximately 7,200 women who served, or about 610 current cases. For both males and females, these rates of current PTSD for theater veterans are consistently and dramatically higher than rates for comparable Vietnam era veterans or their civilian counterparts.

* An additional 11.1 percent of male theater veterans and 7.8 percent of female theater veterans -- 350,000 additional men and women -- currently suffer from "partial PTSD." That is, they have clinically-significant stress reaction symptoms of insufficient intensity or breadth to qualify as full PTSD, but may still warrant professional attention.

* NVVRS analyses of the lifetime prevalence of PTSD indicate that over one-third (30.6 percent) of male Vietnam theater veterans (over 960,000 men) and over one-fourth (26.9 percent) of women serving in the Vietnam theater (over 1,900 women) had full-blown PTSD at some time during their lives. Thus, about one-half of the men and one-third of the women who have ever had PTSD still have it today. These findings are consistent with the conceptualization of PTSD as a chronic, rather than acute, disorder.

* NVVRS findings also indicate a strong relationship between PTSD and other postwar readjustment problems: having PTSD increases the likelihood of having other specific psychiatric disorders and a wide variety of other postwar readjustment problems. These findings confirm that, in addition to the painful symptoms of PTSD itself, the lives of Vietnam veterans with PTSD are profoundly disrupted, in that they experience problems in virtually every domain of their lives.

* The prevalence of PTSD and other postwar psychological problems is significantly, and often dramatically, higher among those with high levels of exposure to combat and other war zone stressors in Vietnam, either by comparison with their Vietnam era veteran and civilian peers or with other veterans who served in the Vietnam theater and were exposed to low or moderate levels of war zone stress. This suggests a prominent role for exposure to war stress in the development of subsequent psychological problems, and confirms that those who were most heavily involved i.

the war are those whom readjustment was, and continues to be, most difficult.

* Vietnam veterans with postwar psychological problems are more likely to have sought mental health care provided by the VA than those without such problems. Such veterans have also made greater use of mental health services in general, both from the VA and from other resources (e.g., private physicians or clinics), with non-VA sources accounting for the majority of their total mental health service use. Nevertheless, very substantial proportions of Vietnam veterans with readjustment problems have never used the VA or any other source for their mental health problems.

Clearly, Mr. Chairman, the NVVRS, in the broad sense, tends to portray "good news" for Vietnam theater veterans in that the majority have made a successful re-entry to civilian life and have experienced few symptoms of PTSD or other readjustment problems and; theater veterans do not differ greatly from their Vietnam era counterparts.

Just as clear, is the fact that a substantial number of Vietnam theater veterans have experienced past or current readjustment problems. We find it alarming that the prevalence of PTSD symptoms are found to be significantly higher among veterans with higher levels of exposure to war zone stressors, black male theater veterans and female theater veterans.

Although VA has come a long way in the treatment of PTSD and continues to implement and expand the treatment available to veterans, we believe more can and should be done. The legislative proposal being considered, as well as certain other actions VA may take administratively have the potential to greatly enhance their ability to treat PTSD.

H.R. 3037

Mr. Chairman, we would like to take this opportunity to acknowledge and extend our appreciation to Congressman Jontz for his timely introduction of H.R. 3037, the, "Veterans PTSD Treatment and Psychological Readjustment Act of 1989."

Section 3 of H.R. 3037 proposes to; (1) expand the Vet Center program by adding at least 20 new centers by 1991 and 20 more new centers by 1994; and (2) adding at least 15 inpatient PTSD treatment units by 1991 and 15 more by 1994.

Mr. Chairman, we are certainly supportive of any reasonable effort to improve the treatment available to veterans and the access to such treatment.

We are particularly supportive of efforts to increase the number of special inpatient treatment units. Clearly, there is a need for expansion of this type of specialized treatment. Also, we are particularly concerned with the exceeding long waiting list and times for veterans to gain access to the care they desperately need.

Although we are supportive of extending services where and when needed based on clearly established and documented need, we are also mindful of the need for system flexibility. Accordingly, we would suggest and favor an approach that provides a degree of flexibility to establish such centers and/or units where a true, documented need exists.

Section 4 would provide for the sum of $10 million -- out of the total Fiscal Year 1990 Readjustment Counseling Service budget allocation of $47 million -- be dedicated exclusively for

the purpose of providing contract care services for veterans in need of readjustment counseling.

Mr. Chairman, we are in complete agreement with the perceived intent of this proposal -- that sufficient funds be available for the treatment of veterans requiring counseling services. However, we are concerned that by requiring the expenditure of funds for only one purpose the entire program's ability to best meet veterans' needs may be jeopardized.

Therefore, we would not favor enactment of this measure if it would result in already scarce medical care dollars being diverted from the operation of Vet Centers to fund contract care that perhaps may not be needed. Clearly, a need exists to sufficiently fund the contract care needs of the program, however, we urge that the current program flexibility to utilize resources be maintained.

Mr. Chairman, we support Section 5 that would require the Secretary to encourage psychiatrists, psychologists and psychiatric nurses, specializing in the treatment of PTSD, to participate in the Health Professionals Educational Assistance Program.

We believe the time has arrived when it is becoming increasingly more difficult to recruit and retain qualified health care providers. This may especially be true when dealing with mental health professionals trained in, or interested in the treatment of PTSD.

Section 6 proposes to add a new section -- Section 225 -- to Title 38, USC, establishing the, "Advisory Committee on Readjustment of Veterans."

Mr. Chairman, the DAV supports this measure. As you well know, such an Advisory Committee now exists, was established administratively and currently reports to the Secretary.

It is our opinion, however, that a statutorily authorized Advisory Committee may be warranted at this time in order to ensure that the needs of Vietnam veterans requiring readjustment counseling and other services are fully met in the most comprehensive manner possible. Also, we believe such an arrangement would serve the Veterans' Affairs Committees and Congress well by prescribing well defined criteria that must be met concerning reporting procedures and providing timely information that would enable you to effectively carry out oversight functions.

Mr. Chairman, the DAV is anxious and willing to work with you and the members of the Subcommittee regarding any "fine tuning" that may be required regarding the language pertaining to the Advisory Committee and its functions.

Section 7 of this measure proposes to establish a pilot program, similar to that in existence for the treatment of substance abuse, for the care of veterans afflicted with PTSD in halfway houses.

Mr. Chairman, the DAV is generally supportive of this proposal. In our view, the successful treatment of veterans suffering with PTSD is best accomplished by providing a full continuum of care, including outpatient services, employment, training, educational and rehabilitation opportunities and temporary housing assistance. We believe the intent of this measure addresses these and other crucial areas.

Again, Mr. Chairman, we would be pleased to work with you and the Subcommittee regarding any "fine tuning" that may be required.

Finally, we are supportive of Section 8 proposing the conduct of appropriate research, through the National Center on PTSD, relating to the treatment of PTSD to include the most effective means of treatment and to coordinate and standardize, where possible, such treatment.

Mr. Chairman, as you well know, PTSD was not specifically identified and recognized, as a disorder, by the psychiatric community until 1980. Prior to that time the symptomatology of what is now recognized and known as PTSD was commonly referred to as "combat fatigue," "battle neurosis," "war neurosis" or "shell shock."

It is our view, Mr. Chairman, that PTSD has been afflicting veterans for as long as wars have been fought. Vietnam veterans are certainly not the first group of veterans to have suffered the symptoms of this disorder. Significant numbers of World War II, Korean and other combat veterans also are afflicted with psychological disturbances that clearly warrant the diagnosis of PTSD.

Mr. Chairman, we find it patently unfair to deny these veterans the full array of mental health services that are provided by the VA. Therefore, we would urge the Subcommittee, if H.R. 3037 is to be favorably reported, to include language authorizing a full continuum of mental health services, i.e. Vet Centers, to all veterans.

Mr. Chairman, one of the most recent methods employed by the VA in addressing PTSD is the PTSD Clinical Team (PCT).

Currently, there are 44 such teams operating in the VA health care system. The PCT is designed to provide specialized outpatient care and consultation liaison services, as well as a level of specialized care that rests somewhere between the most intensive inpatient PTSD treatment unit and the services provided by Vet Centers.

The primary role of the PCT is to evaluate and treat veterans with PTSD, especially those who have had no prior specialized care for PTSD. Also, part of the PCT mission is an educational component both within the parent VA medical center and within the community, as well as a liaison with Vet Centers. Education within the medical center tends to promote and increase the degree of awareness among health care providers not intimately familiar with PTSD cases and thus aids in the referral process.

Mr. Chairman, it is our belief that the VA has an excellent existing resource in both the Vet Center program and the recently created PCT. We believe, and urge the VA to move aggressively in the direction of fully utilizing the services and expertise that currently exists within the system. Additionally, as proposed by H.R. 3037, we also feel an aggressive movement is required to establish new inpatient treatment units where a documented need exists.

The VA has done an admirable job in the area of PTSD concerning treatment, research and educational activities. In fact, the VA has led the way. Clearly more needs to be done and we believe H.R. 3037 provides an excellent vehicle by which the VA may move forward for the purpose of providing quality medical care services to veterans afflicted with PTSD.

Mr. Chairman, this concludes my statement and I would be pleased to respond to any questions you or members of the Subcommittee may have.

STATEMENT OF

VIETNAM VETERANS OF AMERICA, INC.

Presented by

PAUL S. EGAN
LEGISLATIVE DIRECTOR

Mr Chairman and members of the Subcommittee, the Vietnam Veterans of America, Inc. (VVA) appreciates this opportunity to present its views on the issues associated with the treatment of veterans suffering from Post Traumatic Stress Disorder (PTSD). The letter of invitation to this hearing indicates a desire on the part of the Subcommittee to examine three related matters; the capacity of the VA to deliver mental health services, the legislation at hand (HR. 3037) to expand treatment services for PTSD within the VA and the impact of the drug clozapine on the delivery of mental health services.

Mr Chairman, to the extent we are qualified we will attempt to explore these issues. The primary concerns that will be discussed throughout this statement, however, are predicated upon public policy rather than clinical considerations. This being so, we are unprepared to address the issue of the use of the drup clozapine.

Nature and Extent of the Problem

Within the last 15 months two distinguished studies have emerged, each of which clearly demonstrates that PTSD is a debilitating and serious problem affecting Vietnam-era veterans, principally combat theatre veterans. The first of these studies is that conducted at the behest of the VA by the Research Triangle Institute (RTI).

In this study, it is estimated that some 850,000 Vietnam veterans are suffering with either full blown PTSD or some diagnosable set of components of PTSD. The incidence of PTSD in minority veterans is substantially greater than for non-minority veterans but fully 15.2 percent of all Vietnam theatre veterans are

estimated to have PTSD.

Another study published in the March 2, 1990 issue of the Journal of the American Medical Association confirmed the findings of the RTI study in demonstrating that exposure to the stress of combat can be expected to cause PTSD. This particular study compared identical twins. The twins study was conducted by looking at twin pairs both of whom served in Vietnam, neither of whom served in Vietnam and twin pairs in which only one twin served in Vietnam. Comparison of the last of these twins pairs constitutes the meat of the study. It was found among twin pairs involving only one of whom served in Vietnam that the prevalence of PTSD in the twins having served in Southeast Asia was 16.8 percent compared with only 5 percent among the twins who served elsewhere. Among those twins who served in Southeast Asia, there was a ninefold increase in PTSD among those exposed to high levels of combat.

A component of yet another study conducted by The American Legion and Columbia University some years ago also found increased incidence of PTSD among combat veterans. In that study of Vietnam era Legionnaires, an elaborate method was used to score combat and combat related stress. Not surprisingly the individuals with the highest stress scores were the most likely to be afflicted with PTSD.

Collectively these studies show the problem of PTSD to be of epidemic proportions. *They further show that PTSD is clearly related to military service, particularly combat service whether adjudicated as service related or not. From a public policy perspective, it seems obvious that the VA has an overarching obligation to respond by making services and treatment available on a priority basis.

Unless the VA's health care mission has changed from its natural orientation toward treatment of service related disability, it is incumbent upon the VA to bring more of its resources to bear on the PTSD problem.

VA Response to the Problem

In the period since the RTI study was released, very little has been done to address the pressing epidemic of PTSD among Vietnam veterans. Until recently not a single inpatient PTSD unit has been added to the mere 16 that operate among the VA's 172 hospitals. Of the 16 inpatient units that are operating, some have waiting periods for admission of up to two years. Added to this, the VA has failed to make it clear to local hospitals where inpatient PTSD units are operating that these units are an indispensable part of the agency's thrust on the PTSD issue. An illustrative example of this failure to emphasize the importance of PTSD inpatient treatment is evidenced by the plans last winter of the hospital in Topeka, Kansas to close down the inpatient PTSD unit and convert the beds to nursing home beds. Only after the matter was played out in the press was the Central Office willing to turn things around.

Of the 16 impatient units that are operating, there seems little communication between or among these units as to what type of treatment works. Similarly, each seems to operate as the individual fiefdom of each's clinical director. Some of these units are undoubtedly functioning well with veterans receiving the care appropriate to PTSD This, however, seems more by accident than by design or coordination of the VA's Central Office.

Another illustrative indicator of the failure of the VA to give PTSD the priority status it deserves was evidenced last January at the agency's annual briefing on the budget request for the upcoming fiscal year. At that time, much was being made of the additional $1 billion requested for VA health care. When asked if any new resources had been requested for added inpatient PTSD units the then Chief Medical Director didn't know. As it turns out, no new resources had been requested for that specific purpose.

Finally, one additional example was evidenced by the fact that no regularly scheduled quarterly meeting of the VA's Advisory Committee on the Readjustment of Vietnam Veterans was held last May. Insufficient resources in the Medical Administration and Miscellaneous Operating Expenses (MAMOE) budget was given as the reason. The absence of sufficient resources may actually have

necessitated the cancellation of the quarterly meeting of this advisory committee whose principal focus is the treatment of veterans with PTSD, but the fact that the agency is nevertheless prepared to spend millions that apparently are available on the renovation of the Central Office building raises serious questions of whether the agency has it priorities straight.

The VA of late has begun to establish Post Traumatic Stress Clinical Teams (PCTs) in some of its hospitals, but these hold little promise as efficient conduits through which appropriate PTSD treatment can be provided. Most of these PCTs lack the resources needed to carry out their mission. Where they do exist, it is unlikely they can successfully carry out their assigned mission even if resources are made available. It's highly unlikely, in this connection, that these teams will be used for their stated purpose because staff shortages everywhere in VA health care demand that team members be otherwise occupied.

From a practical standpoint, if these teams were to intervene in the operations of a hospital unit where PTSD patients were being improperly cared for, one wonders how they would fare against the opposition of a unit chief or the preferences of a medical affiliation bent more on training residents than on treating veterans. For example, let us assume a general psychiatric inpatient unit was headed by a clinician whose preferred method of treating psychiatric patients was guided by the psychoanalytic teachings of Freud. In this example, the PCT notes the irrelevance of Freudian psychoanalysis to the well established conventions of treatment for PTSD. How is the PCT to prevail if the unit's chief clinician refuses to cooperate?

In another example, let us suppose that a medical school resident on a general psychiatry unit has selected a veteran with PTSD for the purpose of administering Electro-Convulsive Therapy (ECT). Under the circumstances, these decisions are usually made with the concurrence of the faculty of the teaching affiliation. How is the PCT to intervene preventing the effective ECT-induced erasure of the veterans recent memory (recent memory of the

stressful experiences giving rise to PTSD is critical to PTSD treatment) if the resident and teaching affiliation are insistent that the ECT experience is both clinically indicated and necessary for teaching purposes?

Moreover, the VA has failed to meet its obligation to afford appropriate services to veterans with service induced PTSD and has failed to assure appropriate treatment is accorded the priority and coordination of services that are deserved. Too few inpatient units are available and too little coordination of these inpatient units is provided. The alternative offered by the VA's PCT's is inadequate and cannot serve as a substitute for needed investment of more resources and more serious attention to PTSD.

Mr Chairman, after having criticized the practical limitations on the use of PCTs, we are mindful that the existence of some PTSD treatment services where none currently exist is better than nothing. The operational goals of the PCTs, as we understand them, are welcome. Placing PCTs in rural hospitals where Vet Centers and contract care providers are absent makes good policy sense. What we have seen, however, is the establishment of PCT's at hospital facilities where Vet Centers locally are already in place. This is troubling given the outreach and networking component of the state PCT mission.

Outpatient Treatment of PTSD

Since 1979 the VA has been compelled to operate a readjustment counseling service that today encompasses 196 "Vet Centers" around the country. The counseling services provided work well to accommodate the overwhelming lion's share of PTSD outpatient treatment that is provided by the VA. As well as these Vet Centers function, the entire network is only scarcely able to meet demand. The employees working at these Vet Centers are stretched to the breaking point by ever increasing demands by veterans in need of the quality counseling services that have become the hallmark of the Vet Center program. Cities with lesser populations have no Vet Center and rural parts of the country must rely on a contract provider program that has been subject to destabilizing budgetary fluctuations over the years.

The Vet Center program is a proven way to provide outpatient counseling services but it is too small and its budgets over the years have failed even to keep with incrementally rising operating expenses. Against this background, the RTI study tells us that scarcely 10 percent of those veterans in need of counseling services have ever availed themselves of the VA. It may be true that many veterans refuse to acknowledge a need for treatment, but the more likely reason veterans have stayed away from the VA is that too few Vet Centers are conveniently available.

The Vet Center currently operates on a budget of $47 million. This is hardly a severe budgetary burden for such a successful program. The seemingly miraculous fact is the Vet Centers work well in abating PTSD and they don't break the bank in the process.

HR. 3037

Thusfar, the parameters of the PTSD epidemic have been outlined. It is clear that the VA's response has been inadequate. It is also clear that more must be done. In our opinion, HR. 3037 is a thoughtful approach to the PTSD epidemic that proposes meaningful steps toward a resolution without requiring huge infusions of federal resources.

This bill proposes expanded inpatient and outpatient treatment and both are desperately needed. Inpatient units operated by the VA medical centers would be increased in number from 16 to 46 by adding 30 units over the course of four years. For a hospital system of 172 hospitals facing an epidemic of PTSD, this is hardly outlandish.

Outpatient services would be expanded by capitalizing on what we already know works well. The readjustment counseling service would be expanded from 196 Vet Centers to 236 by adding 40 new Vet Centers over the course of four years. Again this is hardly outlandish.

Importantly, the bill would also designate one new inpatient unit as a treatment research unit. Since, as described earlier, little coordination among the existing inpatient PTSD units takes place, the addition of a single treatment research unit would serve in the capacity of a coordinating clearing house for the

treatment provided by VA inpatient units as a whole.

Moreover, the need for a treatment research unit cannot be diminished. To date hundreds of studies have been conducted to ascertain a better understanding of the pathologic or pathogenic character of PTSD but nearly no research has been undertaken to ascertain information on what treatment modalities veterans respond to best. This unit would be dedicated to the exclusive purpose of doing just that.

The inadequacy and instability of the contract provider program is also wisely addressed in HR. 3037. The bill would mandate budgetary stability that is long overdue. The importance of this provision to rural veterans as well as to contract counseling providers remote from Vet Centers cannot be overstated. In the past, the VA has offered the availability of contract funds in order to attract qualified contract providers. Unfortunately, once these providers begin to work with rural veterans, budget cuts make it impossible to retain all of the providers originally attracted to the program. This results in discontinuity of treatment, diminished service to rural veterans and creates the impression among providers that the VA cannot be trusted.

Section 5 of HR. 3037 would authorize the VA to offer scholarships to individuals interested in attending academic and clinical education programs designed to train personnel in the treatment of PTSD. This provision is necessitated by the fact that too few qualified PTSD treatment professionals exist in either the public or private sectors to address the PTSD epidemic. Individuals in receipt of VA scholarships would be required to invest a few years with the VA in the treatment of veterans with PTSD. It is intended that many of these trained personnel would fill out the staffs of the new inpatient PTSD units.

Section 6 of HR. 3037 would codify the VA's existing Advisory Committee on the Readjustment of Vietnam Veterans by expanding its scope and assuring its continuation as a statutory requirement. The reason for this provision is to assure that it remains a vital source of valuable information on the readjustment of veterans.

The fact that the May 1990 quarterly meeting was canceled should serve as strong enough evidence that this Advisory Committee's existence is vulnerable and deserves statutory protection.

The VVA, however, strongly recommends that any ex officio representation on the committee by political appointees under the terms of the legislation be non-voting representation. The dismal history of another Advisory Committee operated at the Department of Labor, the Secretary's Committee on Veterans Employment (SCOVE), serves as a good example of how political appointees as voting committee members have subverted the ability of that particular committee to serve in a legitimate advisory capacity. Each time a motion has been offered that contradicted the Administration's budget proposals, the committee has become paralyzed, unable to conduct business or examine programmatic issues. The overriding concern necessitating this provision of HR. 3037 is the preservation of the committee as it is currently constituted and as it currently operates. We fully embrace a change in the name of the Advisory Committee, however, to reflect an expanded scope to include readjustment of more than just Vietnam veterans.

Mr Chairman, that concludes our statement.

American Association for Marriage and Family Therapy

STATEMENT OF RALPH H. EARLE, PH.D., PRESIDENT
AMERICAN ASSOCIATION FOR MARRIAGE AND FAMILY THERAPY
IN SUPPORT OF THE EXPANSION OF POST TRAUMATIC STRESS DISORDER SERVICES
PROVIDED BY THE DEPARTMENT OF VETERANS' AFFAIRS

SUBMITTED TO THE SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE
OF THE HOUSE VETERANS' AFFAIRS COMMITTEE

JUNE 28, 1990

Mr. Chairman and distinguished members of the Subcommittee, I am Ralph H. Earle, Ph.D., the President of the American Association for Marriage and Family Therapy (AAMFT). My statement is submitted on behalf of the 17,500 members of AAMFT, the national professional association of qualified practitioners of marriage and family therapy.

I appreciate having this opportunity to comment on deficiencies in the delivery of mental health services at the Department of Veterans' Affairs (DVA) and, particularly, the critical need to expand the Department's provision of Post Traumatic Stress Disorder (PTSD) services to veterans and their families.

It is estimated that over 800,000 Vietnam-era veterans suffer from Post Traumatic Stress Disorder, yet only ten percent of these veterans or their families have received mental health treatment through the Department of Veterans' Affairs to resolve the profound problems associated with the disorder. It is clearly time for the Department to make major changes in the way that it views the treatment of PTSD and, more broadly, to place greater emphasis on providing the most appropriate diagnosis and treatment for mental and emotional disorders.

Your Subcommittee colleague, Jim Jontz deserves much praise for his efforts to bring this important issue to the forefront of the House Veterans' Affairs Committee's agenda. AAMFT has endorsed Mr. Jontz's legislation, the Veterans' PTSD Treatment and Psychological Readjustment Act, H.R. 3037, which seeks to improve access to needed PTSD treatment services by expanding the number of inpatient and outpatient PTSD treatment facilities within the Department of Veterans' Affairs.

Mr. Jontz's bill also addresses the Department's need for additional mental health personnel by directing DVA to provide scholarships and training opportunities to mental health professionals trained in each of the five federally-recognized mental health disciplines (i.e. marriage and family therapy, psychiatry, psychology, social work and psychiatric nursing) to facilitate the provision of PTSD treatment services to veterans in need. This Association urges the Subcommittee to approve this legislation as expeditiously as possible.

Post Traumatic Stress Disorder was recognized as a diagnosable mental disorder in the Diagnostic and Statistical Manual of Mental Disorders (DSM-III) in 1980. PTSD is characterized by symptoms including recurrent nightmares, intrusive thoughts, or flashbacks of a traumatic event; depression; phobic behavior or generalized apathy; feelings of detachment or estrangement from others; sleep difficulties; difficulty in concentrating; and irritability or outbursts of anger. (Figley, 1989) Onset of symptoms may occur immediately after a traumatic event or may emerge months or years later.

Despite the legitimacy of the diagnosis, the Department of Veterans Affairs has been very reluctant to address the needs of veterans' with PTSD and to provide adequate resources because of the lack of personnel and a clear mandate and pressure from Congress.

The Department has been even more reluctant to address the problems associated with a diagnosis of Post Traumatic Stress Disorder from a family systems perspective. Research findings and common sense indicate that the

disorder has a profound impact on the family members of veterans' suffering from PTSD, that dysfunctional family dynamics may exacerbate the problems of the veteran with PTSD, and that the family can and must receive treatment together with the veteran to best promote and sustain recovery. It is incumbent upon the Department to reconceptualize the treatment of veterans suffering from PTSD and to promote treatment from a family therapy perspective.

Charles Figley, Ph.D., a Vietnam veteran and marriage and family therapist and researcher, is acknowledged internationally as the expert on the treatment of Post Traumatic Stress Disorder. Dr. Figley is currently the Director of the Marital and Family Therapy graduate program at Florida State University and is the editor of the Journal of Traumatic Stress. He has a long history with the Department of Veterans' Affairs and was instrumental in the creation of the outreach program to veterans with PTSD in 1979.

As Dr. Figley, a Fellow and Approved Supervisor in AAMFT, notes in his most recent book, Helping Traumatized Families (1989), families are the first to detect trauma-related trouble, the first to try to help, and the most adversely affected because of it. Just as a family member -- especially a parent and wage-earner -- is impaired by drug or alcohol dependency, veterans affected by PTSD function poorly in their family roles. Moreover, a part of the syndrome is violent outbursts. Unfortunately, family members absorb the majority of the abuse.

For the past 15 years, Figley and others have studied the immediate and long-term effects of traumatizing experiences on both individuals, families, and their supporters. Their conclusions are that all estimates of the number of people traumatized are greatly underestimated; that these statistics hide the fact that supporters in general and family members in particular are the secondary victims of traumatizing events.

With regard to war, the published estimated of PTSD recently published in Trauma and the Vietnam War Generation (Kulka, Schlenger, Fairbank, Hough,

Jordan, Mammar, and Weiss, 1990), confirm the fact that family members are most affected by members with PTSD. Kulka, et. al. note:

> For example, 69.9% of men with PTSD had been divorced, 22.4% two or more times, compared with only 34.9% and 8.1%, respectively, among those not suffering from this disorder. For women, the comparable proportions were 79.1% versus 26.7% and 10.6% versus 3.3% respectively. In addition, men with PTSD also reported higher levels of parenting problems and significantly poorer family adjustment (even without children). Among theater veterans with children, over half (54.8%) of those with PTSD described their families as extreme (that is, more poorly functioning) on both adaptability and cohesion, compared with only 19.3% of those without PTSD. Comparable proportions for all couples were 49.2% and 21.09% respectively.

Because the family system is the unit most adversely affected by trauma, it is logical that it is the unit requiring most attention in treatment. Traditional approaches help the veteran to reconnect cognitively and emotionally with the traumatizing experience of war and the years of efforts to cope. This is done through individual and group counseling sessions. Efforts are made to help the veteran to make sense out of the past and begin to master these troubling experiences and memories. As noted by Figley in his 1978 book, Stress Disorders Among Vietnam Veterans, these veterans are attempting to answer five fundamental questions: 1) What happened? 2) Why did it happen? 3) Why did I act as I did during the war? 4) Why have I acted as I have since the war? and 5) What if something like that {in the war} happens to me again—will I be able to cope? By doing so he or she may be able to develop a "healing theory," a life perspective that will allow him or her to actually benefit from these traumatizing experiences and go on to live full and productive lives.

A more family-centered approach recognizes the need for recapitulation and developing a healing theory. Moreover, there is an important place in a treatment plan for individual and group work. However, the fundamental

focus is on how the family system and its members have been affected by the trauma and attempting, in the end, to develop a family healing theory.

Charles Figley (1989) outlines a five-phase treatment approach to helping traumatized families, including the families of veterans suffering from PTSD. Indeed, the initial major case example used in his book is about a veteran who had been suffering from the delayed effects of PTSD and how it took threats of suicide by the daughter to bring attention to the suffering experienced by himself and all of his family members caused in part by his war experiences 12 years earlier.

Figley's 1978 book helped support long-term efforts in Congress to establish a national mental health services outreach program for Vietnam veterans. As he notes in his writings, Figley found the support of Max Cleland, VA Administrator in the Carter Administration, to be especially effective in generating support within the VA for enactment of S. 7, the legislation that established the Readjustment Counseling Program (Public Law 96-22, 1979). Figley chose to remain an advisor and trainer to the VA during the early years of the program, and he and others were successful in insuring that the family received attention. All of the initial training of new employees insured that they received information and skills in assessing and treating family relationships.

AAMFT has two major concerns with the current state of PTSD treatment within the Department of Veterans Affairs. First, it seems that there has always been a hostile relationship between the Readjustment Counseling Program with its national chain of Vet Centers and all other elements within the VA system. Moreover, it seems that there has always been the intention on the part of the VA to absorb the Program and its Centers within the VA Medical Centers' outpatient mental hygiene clinics. The DVA believes that this is a better method (cost-effective mostly) of providing services. Most vets disagree, particularly Vietnam veterans who have always been suspicious of government services. Moreover, by being incorporated within the traditional VAMCs, the Vet Centers will lose their identity and mission of service to Vietnam vets in particular and combat vets and their families in general.

Second; for years, marriage and family therapists in the outpatient Vietnam Veterans' Readjustment Counseling Centers and in private practice have been providing treatment to veterans and their families who are suffering from Post Traumatic Stress Disorder. As noted earlier, the Vet Center Program has always placed a strong emphasis on family-based treatment of PTSD and, accordingly, has recruited marriage and family therapists to serve on multidisciplinary treatment teams. However, because the federal government has not yet created a General Schedule (GS) series or job title for these professionals, the Vet Centers have been forced to recruit and hire family therapists under a confusing, miscellaneous hiring category.

At the same time, the DVA hospital system has, for all intents and purposes, barred marriage and family therapists from employment in the VAMCs, citing the lack of a federal GS series for the profession. This situation presents a Catch-22 for professionals trained in the federally-recognized mental health discipline of marital and family therapy: the DVA recognizes family therapy as a service for its clients but actively chooses not to hire those professionals who are trained to provide this service, along with a wide range of other mental health services.

Marriage and family therapists diagnose and treat a broad array of mental and emotional disorders, ranging from serious mental illness, to Post Traumatic Stress Disorder, to substance abuse, to other forms of psychopathology, working with individuals and/or families, within a systems framework. Marriage and family therapists are also as capable of doing intake and assessment, case management and other related functions as are other mental health professionals recruited and hired by the DVA.

It is within the DVA's power to rectify this situation by requesting that the Office of Personnel Management (OPM) create a new GS series for marriage and family therapists. This action would not result in increased federal costs. In fact, the creation of a GS series would merely allow the Department to recruit from an expanded pool of qualified professionals for existing mental health positions, a goal which is clearly present in Rep. Jontz's PTSD treatment bill, H.R. 3037.

AAMFT believes that DVA's apparent discriminatory bias against those trained in the mental health discipline of marital and family therapy denies appropriate recognition of the skills and training of family therapists, and does not adequately reflect the state of mental health training or private marketplace recognition in 1990. DVA's apparent institutional bias against recruiting and hiring from as broad a pool of well-qualified mental health professionals as possible flies in the face of the Department's chronic need for personnel and denies many veterans' and their families access to appropriate mental health services.

Conclusion

It is critical that the DVA reconceptualize the treatment of PTSD and other mental disorders and end its traditional heavy emphasis on a "medical model" of treatment based on individual illness. Paul Errera, M.D., the Director of DVA's Mental Health and Behavioral Sciences Service, has acknowledged the need to treat veterans, be they mentally ill, homeless, aged, or suffering from Post Traumatic Stress Disorder or substance abuse, in the context of their community and family. Providing treatment in the context of an individual's situation -- what is commonly recognized by the DVA as "systems" treatment -- is precisely what marriage and family therapists are trained to do.

Mr. Chairman, the American Association for Marriage and Marriage and Family Therapy urges you and your colleagues on the Subcommittee on Hospitals and Health Care to take the following actions:

1) give swift approval to H.R. 3037, the Veterans' PTSD Treatment and Psychological Readjustment Act, sponsored by Jim Jontz (D-IN) to improve access to needed PTSD treatment services for affected veterans and their families by expanding the number of inpatient and outpatient PTSD treatment facilities within the Department of Veterans' Affairs; the bill also addresses the Department's need for additional mental health personnel by directing DVA to provide scholarships and training opportunities to mental health

professionals from the five federally-recognized mental health disciplines (i.e. marriage and family therapy, psychiatry, social work, psychology and psychiatric nursing) to facilitate the provision of PTSD treatment services to veterans in need; and

2) direct the Department of Veterans' Affairs to end its discriminatory recruiting and hiring practices against marriage and family therapists. Veterans and their families would be best served by having access to mental health professionals trained in each of the five federally-recognized core mental health disciplines. AAMFT urges the Subcommittee to direct DVA to work with the Office of Personnel Management in the creation a GS series for marriage and family therapists, so that this important goal might be accomplished.

Mr. Chairman, on behalf of the 17,500 members of the American Association for Marriage and Family Therapy, I thank you for your leadership in addressing these important issues. This Association stands ready to assist you and and the other distinguished Members of the Subcommittee in improving the delivery of Post Traumatic Stress Disorder and other mental health services for veterans and their families in Department of Veterans' Affairs facilities.

Sandoz Pharmaceuticals Corporation
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August 6, 1990

Honorable G.V. Montgomery, Chairman
U.S. House of Representatives
Committee on Veterans' Affairs
335 Cannon House Office Building
Washington, DC 20515

Dear Mr. Chairman:

We are pleased to be able to answer your letter of July 11, 1990. In that letter, you requested as a follow up to the June 28 Subcommittee hearing on Hospitals and Healthcare, that we provide answers to four specific questions. These answers are attached.

It was a pleasure to meet with members of your Committee on June 28, and welcome the opportunity to clarify our position. Thank you for your continued interest in CLOZARIL and treatment-resistant schizophrenic patients.

Very truly yours,

Denis M. Grady

DMG:js

Enclosure

WRITTEN COMMITTEE QUESTIONS AND THEIR RESPONSE

RESPONSES TO QUESTIONS SUBMITTED BY
HONORABLE JOHN PAUL HAMMERSCHMIDT
TO SANDOZ PHARMACEUTICALS CORPORATION
AT THE SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE
JUNE 28, 1990
PTSD

1) The VA is the largest health care delivery system in the nation. It is closely linked by computer as well as through a central office here in Washington. It seems to me that the VA is a unique system which could provide the same if not, better oversight on CLOZARIL's side effects through a uniform, national risk management protocol. Do you agree that the system is unique in these respects?

Response: The VA healthcare delivery system is certainly the largest in the country. As such, it is comprised of many discrete service elements (hospital, outpatient clinics, etc.) as well as providing services on a sub-contract basis with local practitioners in the case of veterans and their beneficiaries who are not fortunate enough to live close to VA treatment facilities.

Sandoz' primary concern, a concern shared equally by the VA, is the health and welfare of all patients. This concern for providing the highest possible level of medical care and safety was the driving force behind the testing and introduction of the Clozaril Patient Management System. Given the geographic dispersion and heterogeneous staffing patterns that characterize the VA's nationwide system, we are certain that you share our concern that no VA patient's life be put on the line in an untested, unproven system.

Yes, the VA healthcare system is unique, as is vulnerability to CLOZARIL-induced agranulocytosis (and its proven fatal potential). In the 6 months since commercial introduction, there have been over 60 cases of serious blood reactions due to CLOZARIL, any one of which could have progressed to a fatal endpoint. With CPMS, all cases were promptly identified, and all patients survived. This safety record must be preserved.

2) Is it the intention of Sandoz to attempt to work out a solution with the Department of Veterans Affairs, so that the VA can monitor CLOZARIL through its own VA Clozaril Patient Management System?

Response: Sandoz would like to assess the possibility of the VA's assumption of specific CLOZARIL patient monitoring functions. As a member of Congress, you are all too acutely aware of promising programs which look terrific on paper, but fail in practice. With this dangerous drug, failure could mean veterans' lives lost unnecessarily. Clearly, pilot-testing new procedures is a critical requirement, and VA indemnification of Sandoz against liability claims is a prerequisite to implementation of any system other than CPMS.

3) What are Sandoz' specific plans to work with the VA?

Response: Sandoz remains receptive to the VA's pilot testing its proposed program under accepted study guidelines. As a prerequisite, however, our Legal Department continues to work with the VA's lawyers on the crucial issue of indemnification. While Sandoz stands fully behind the CPMS system from a liability perspective, we expect to be held harmless in the event of all "misadventures" related to use of CLOZARIL in any proposed VA monitoring system. This issue, like appropriate pilot-test and evaluation, is obviously among the critical issues that must be resolved before discussions proceed. Guaranteed freedom from liability was promised on several occasions by Dr. L. Lehman of the VA Central Office, most recently at the Veterans Affairs Sub-committee Hearings, chaired by the Honorable Mr. Rowland. If this hurdle can be overcome, we would be prepared to consider looking at alternative monitoring possibilities.

4) Why is there no patient monitoring system in Europe for those using CLOZARIL?

Response: There are specific safety procedures in place in all countries in Europe where CLOZARIL (Leponex) is sold. These procedures vary since each country has its own regulatory agency, similar to our FDA. Drug distribution rules are worked out on a nation-by-nation basis between the company and appropriate, national regulatory bodies.

American Pharmaceutical Association
APhA
2215 Constitution Avenue, NW
Washington, DC 20037
(202) 628-4410 FAX (202) 783-2351
The National Professional Society of Pharmacists

July 31, 1990

The Honorable G.V. (Sonny) Montgomery
Chairman
U.S. House of Representatives
Committee on Veterans' Affairs
335 Cannon House Office Building
Washington, DC 20515

Dear Mr. Chairman:

Thank you for the opportunity, both to testify before the Subcommittee on Hospitals and Healthcare on June 28 of this year, and for the opportunity to follow up on the questions that you raised in your letter to me of July 11. I am pleased to provide the attached answers in response to those questions.

We again applaud the work of the Committee and Subcommittee in examining the issue of restricted distribution of clozapine and hope that our mutual efforts will result in a solution to this serious problem. Please feel free to follow up with us if we may be of further assistance.

Sincerely yours,

John A. Gans, Pharm.D.
Executive Vice President

JAG/cew

Enclosures: (1) Responses
(2) FDA correspondence to Sandoz of July 13

Responses of the
American Pharmaceutical Association
to questions regarding clozapine/CPMS
U.S. House of Representatives -- Committee on Veterans' Affairs

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Q.1. You have referred to the Clozaril Patient Management System (CPMS) as monopolistic. Could you explain this further?

A.1. The "Clozaril Patient Management System" (CPMS) restricts the process of drug procurement, distribution and certain patient monitoring functions to a single commercial organization, the Caremark Home Care subsidiary of Baxter Healthcare, Inc. The usual processes for drug procurement, distribution and patient care delivery through the nation's community and hospital pharmacies are circumvented. Rather than utilizing the many qualified community and hospital pharmacists in the U.S., patients are required to obtain both drug therapy and monitoring services only through the restrictive distribution system created by the contract between the drug's manufacturer, Sandoz, and Baxter Healthcare.

Q.2. What have you heard from State Medicaid agencies concerning the CPMS?

A.2. State Medicaid agencies have serious legal, administrative and financial concerns with CPMS. Paying for clozapine under the current financial constraints faced by many programs would either bankrupt many of the programs or force them to make difficult choices between clozapine/CPMS and other important medications and services currently provided. Many state Medicaid programs are precluded by state law from paying for the "bundled" package of medication and laboratory/monitoring services which constitutes CPMS. The development of clinical and administrative procedures to circumvent current requirements are both expensive and inefficient for the states.

Q.3. Do you know how much of the $9,000 in annual costs for Clozaril through CPMS goes to (1) patient monitoring, and (2) the drug?

A.3. No. No one with whom we have communicated has been able to identify the component costs and charges for CPMS. This is the only approved drug in the United States for which health professionals do not have information on direct or wholesale costs of the drug product.

Q.4. Could other providers of Clozaril offer the same safeguards for patients against aganulocytosis that Sandoz maintains Caremark offers?

A.4. Yes. APhA is certain that there are numerous pharmacists and pharmacy care systems in the United States that have or are capable of establishing systems which would provide the linkages of prescribing, dispensing and laboratory data assessment to provide clozapine in accordance with FDA's requirements.

Q.5. You said FDA did not require CPMS as a condition of approval of Clozaril. Why is CPMS specifically contained now in the labeling?

A.5. References to CPMS in the product labeling occurred as a result of the FDA's acceptance of that language as proposed by Sandoz. In communications with APhA in March of this year, FDA characterized the reference to CPMS in the labeling as applying to any system which Sandoz chooses to recognize which provides the required linkage of dispensing to the process of white blood cell sample collection. Of note, FDA has recently sent a letter to Sandoz (July 13--see attached) requesting changes in the labeling which would delete references to the service-marked CPMS entity, and replace them with more generic descriptions of the monitoring processes required by FDA.

Q.6. You refer to "fragmentation" of pharmacy care. Can you give us some further explanation of this concept?

A.6. Pharmacists and physicians have the responsibility to provide comprehensive care to their patients. Pharmacists have the knowledge and responsibility to monitor patients for all drugs they are taking (which are known to the pharmacist), for numerous side effects and potential drug interactions of clinical significance. By focusing only on clozapine and only one of the several significant side effects of the drug, CPMS, if effective at all, addresses only one very small part of the complex drug therapy management often employed for psychiatric patients.

Q.7. What examples of regular monitoring of drug therapy are similar to those suggested for clozapine?

A.7. Many drugs such as digoxin, theophylline and aminoglycosides require frequent monitoring to assure appropriate therapeutic effects and minimization of toxicity. The anticoagulant warfarin (Coumadin) frequently requires weekly assessments of blood clotting times to prevent significant risks of hemorrhage. There are scores of others for which pharmacists have daily responsibility to assure safe and effective use.

Q.8. How does this system infringe on the practice of pharmacy and of medicine?

A.8. In what we view as a precedent-setting step, the FDA has established in a product's labeling the absolute requirement of performance of a specific medical procedure on a specific and inviolate schedule (i.e. a weekly white blood cell analysis) -- regardless of the professional judgement of the physician or pharmacist, regardless of the several other potential contributors to a falling white count which a patient might have, and regardless of whether the physician and pharmacist feel that the current benefits of therapy outweigh the risks to that patient. Without a change in labeling, even if data becomes available from the professional community that a less (or more) frequent monitoring program is appropriate, health professionals will be bound by the labeling of the product with regard to the performance of this medical procedure. We believe that such restrictions on the practice and judgement of health professionals are unnecessary and inappropriate.

0028K/27-28/CEW

DEPARTMENT OF ~~HEALTH &~~ HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-758

JUL 13 1990

Sandoz Pharmaceuticals Corporation
Attention: Hedy M. Ries
Route 10
East Hanover, New Jersey 07936

Dear Ms. Ries:

The wording of certain sections of Clozaril's product labeling is causing considerable confusion and misunderstanding among practitioners and third party health care institutions concerning both the nature and requirements of the so-called 'Clozaril Patient Management System,' also described in labeling as the 'CPMS.'

As currently written, Clozaril's labeling allows the incorrect inference that the product's distribution and sale is only permissible under a system of services provided by a single, specific vendor. In this regard, the labeling is misleading.

FDA's approval of the Clozaril NDA took into account the fact that Clozaril would only be distributed under a system that limits the actual delivery of Clozaril to those patients who have weekly white blood counts performed. Indeed, it was because of the protections offered by such a system of restricted distribution that the agency was able to conclude that Clozaril, a drug known to cause a cumulative incidence of agranulocytosis exceeding one percent per year, would be "safe for use" under its proposed labeling.

Critically, however, the agency's approval of the Clozaril NDA under the labeling proposed did not constitute an approval of a specific vendor for the system of services referred to as the 'CPMS.' To the contrary, we view the term 'CPMS' as a notation for any distribution system that reliably links the the actual delivery of Clozaril to the patient to his or her compliance with a blood testing program.

Your use of a single source vendor for the distribution of Clozaril has contributed to the confusion created by the somewhat ambiguous description of the CPMS in current labeling which allows the inference that the distribution systems identified is a specific entity. Therefore, in order to reduce misunderstanding among patients, prescribers and health care providers, we ask that you expeditiously modify Clozaril's labeling by replacing references to CPMS with more general descriptions of the essential elements of an acceptable system. Such changes are essential if the labeling is to describe the nature of the approved distribution system or systems accurately.

There are currently four references to CPMS in Clozaril labeling, i.e., three in Warnings and one in How Supplied. Three of the references pertain to the actual distribution of Clozaril, while the fourth simply mentions CPMS in the context of a statement regarding the existence of a national master file that seeks to prevent the rechallenge of patients with prior episodes of neutropenia. We ask that you modify these references as follows:

1. Last paragraph of 'General' subsection of Warnings:

   We ask that you replace this paragraph with the following:

   > Clozaril is available only through distribution systems that ensure weekly WBC testing prior to delivery of the next week's supply of medication.

2. Sixth paragraph of 'agranulocytosis' box in Warnings:

   We ask that you modify the last sentence in this paragraph by deleting the phrase 'within the CPMS (Clozaril Patient Management System).'

3. Last paragraph of 'agranulocytosis' box in Warnings:

   We ask that you replace this paragraph with the following:

   > To reduce the risk of agranulocytosis developing undetected, Clozaril is available only through distribution systems that ensure weekly WBC testing prior to delivery of the next week's supply of medication.

4) First paragraph of How Supplied:

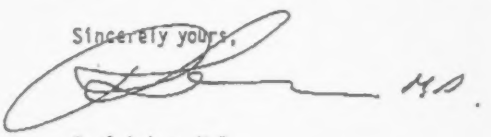
   We ask that you replace this paragraph with the following:

   > Clozaril is available only through distribution systems that ensure weekly WBC testing prior to delivery of the next week's supply of medication.

We ask that these changes be implemented immediately.

If you have any question please contact Ms. Sharon Norris, Consumer Safety Officer at (301) 443-3830.

Sincerely yours,



Paul Leber, M.D.
Director
Division of Neuropharmacological
Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Texas Department of Mental Health and Mental Retardation
Central Office
P.O. Box 12668 • Austin, TX 78711-2668 • (512) 454-3761

Dennis R. Jones, M.S.W., M.B.A.
Commissioner

October 1, 1990

The Honorable G. V. Montgomery
Chairman
Committee on Veterans' Affairs
U. S. House of Representatives
335 Cannon House Office Building
Washington, D. C. 20515

RE: Your Letter of July 11, 1990; Subcommittee on Hospitals and Health Care

Dear Congressman Montgomery:

First, I must apologize for not answering your request for additional information in a timely fashion. I appreciated the opportunity to testify before your subcommittee, and am happy to supply the material below.

1. Due to the increasing number of veterans seeking treatment for PTSD and a shortage of resources, the Department of Veterans' Affairs (DVA) has significantly reduced its length of stay for inpatient PTSD treatment. Has this reduction led to higher recidivism rates among those veterans who have received treatment?

Answer: I do not have data available to answer this question. I understand that VA recidivism reports concerning patients with PTSD may be available, and that the chief medical director's Special Committee may be doing such a study at this time.

2. At the hearing, the balance between the capacity for inpatient and outpatient care for PTSD was discussed. Please elaborate on how you would recommend the distribution of any new PTSD treatment monies between inpatient units, outpatient units, veterans' centers, outreach efforts, and other types of care.

Answer: I strongly recommend an array of services, each of which appoints levels and types of alternative care to match the changing needs of this group of chronically ill veterans. The levels and ranges should go from the most intensive inpatient care to specialized outpatient treatment of PTSD (including outreach services). Inpatient psychiatric services should not be allowed to suffer in this distribution of resources.

3. What are your views (including data if available) on the availability of staff for PTSD treatment if such treatment capacity were expanded as proposed in H.R. 3037 for the following: inpatient units, outpatient units, vet centers, other?

Answer: It is my understanding that there are present and continuing difficulties in recruiting psychiatrists, psychologists, and nurses to VA service. The recruitment problems appear to be related to differences in salary between VA positions and positions outside the VA system. Beyond issues of salary, however, clinical professionals feel it is important to be working within a system that provides an adequate range and quality of care. If treatment capacity were expanded for any of the kinds of units and centers mentioned, staff availability should increase.

4. Would you support the idea of central funding for PTSD treatment centers as opposed to funding as part of each VA center's annual budget allocation? If not, why not?

Answer: The value of central funding is the ability to insure that monies are spent as VA policy intends. On the other hand, this can limit the ability of individual VA medical centers to be flexible and innovative. Patients are the important issue here. I have some concerns that central funding for PTSD treatment centers would be vulnerable to redirecting of those dollars for other needs (such as capital improvements).

Thank you for the opportunity to comment. I should be happy to respond further to you or any member of the Subcommittee.

Cordially,

William H. Reid, M.D., M.P.H.
Medical Director

Professor of Psychiatry and
Special Assistant for Mental Health
and Mental Retardation Affairs
The University of Texas System

WHR:sfm

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American Psychological Association

Advancing psychology as a science, a profession, and as a means of promoting human welfare

August 6, 1990

G.V. (Sonny) Montgomery, Chairman
Committe on Veterans' Affairs
Subcommittee on Hospitals and Health Care
335 Cannon House Office Building
Washington, D.C. 20525-6335

Dear Chairman Montgomery,

On behalf of the American Psychological Association and the Association of V.A. Chief Psychologists, I am pleased to forward to you our answers to the additional questions regarding Post Traumatic Stress Disorder Treatment (PTSD). We appreciate the opportunity to provide further input on PTSD treatment and research needs within the VA health care system. Attached is a copy of the APA and AACVAP's joint answers together with the questions as requested.

If we can provide additional information to the Subcommittee, please do not hesitate to call Sarah Lynn of the APA's Practice Directorate at (202) 955-7618.

Sincerely,

Kenneth Klauck, Ph.D.

1200 Seventeenth Street, N.W.
Washington, DC 20036
(202) 955-7600

American Psychological Association

Advancing psychology as a science, a profession, and as a means of promoting human welfare

POST-TRAUMATIC STRESS DISORDER

QUESTIONS AND ANSWERS PROVIDED BY THE AMERICAN PSYCHOLOGICAL ASSOCIATION

AND THE

ASSOCIATION OF VA CHIEF PSYCHOLOGISTS

1. Due to the increasing number of veterans seeking treatment for PTSD and a shortage of resources, the Department of Veterans Affairs (DVA) has significantly reduced the length of stay for inpatient PTSD treatment. Has this reduction led to a higher recidivism rate among those veterans who have received treatment?

Because of the nature of PTSD, it is difficult to predict which set of circumstances will stimulate a relapse. Shortened lengths of stay on inpatient programs do not necessarily increase recidivism provided there is sufficient follow up and support on an outpatient basis. We do not have any research data on this topic, however, the Chief Medical Director's Special Committee on PTSD was Congressionally mandated in 1985 to respond to this issue of recidivism and plans to publish some data this Fall.

In general, inpatient treatment programs provide access to both biological intervention and intensified psychological/social programming. While there is not yet a developed consensus on biological/medication treatment approaches, there is consensus that psychological interventions are effective. Psychological treatment approaches require longer lengths of stay than is typical for most psychiatric disorders and require a well-developed program of aftercare using such resources as Post-Traumatic Stress disorder Clinical Teams (PCT's), Post-Traumatic Stress Disorder/Substance Use Disorder programs (PSU's), domiciliaries, and transitional living programs. In our judgment, a well-established continuum of care can reduce the length of stay on inpatient treatment programs and positively impact the treatment of veterans with PTSD.

2. At the hearing, the balance between the capacity for inpatient and outpatient care for PTSD was discussed. Please elaborate on how you would recommend the distribution of any new PTSD treatment monies between inpatient units, outpatient units, vet centers, outreach efforts, and other types of care.

As we testified, programs should only be expanded if services are lacking and a need has been demonstrated. However, because advances in treatment usually result from research, funds need to be distributed to those areas which can most successfully integrate research and clinical treatment. An additional requirement for successful treatment is the quality of the professional staff involved in providing the treatment. In this regard, the medical centers have been able to attract more qualified professionals for both inpatient and outpatient programs than vet centers and other various outreach efforts. Although the vet centers have been in existence for almost ten years, little research has evolved from this program and the centers continue to have staff qualifications which require less training and experience. Some sections of the country do not have inpatient treatment programs in their geographical area, but do have a need for them. These programs are needed to provide access to care for all veterans. Providing services in the least restrictive environment is always preferable, and therefore, new monies should be used to increase outpatient services with solid professional support such as medical center-based PCT's and PSU's. In our judgement, primary emphasis should be focused on providing follow-up and aftercare programs, specialized treatment units, and vet centers in that order.

3. What are your views (including data if available) on the availability of staff for PTSD treatment if such treatment capacity were expanded as proposed in H.R. 3037 for the following: Inpatient units, outpatient units, vet centers, other?

The quality of the treatment staff is the critical factor in any program whether it is inpatient or outpatient. Although nursing and psychiatry shortages are well known, there are also problems emerging in recruiting clinical and counseling psychologists into the VA system. A recent survey conducted by the Association of VA Chief Psychologists in March, 1990, found that there was a 11.6% vacancy rate for clinical and counseling psychologists in the Veterans Health Services and Research Administration (VHSRA). This rate is 1.5 times the vacancy rate occurring in October of 1988. Recruitment takes an average of six months and only 50% of the vacancies are filled within that time period. Low salaries and lack of career advancement opportunities contribute to both recruitment and retention problems. About one-third of the new hires terminate their appointments within the first five years.

Problems in attracting qualified staff are even worse at vet centers where there are psychologists at only one-third of the locations; for a total of 52 doctoral-level psychologists. There are very few psychiatrists working at vet centers.

While we cannot speak for other professions, psychology interns are regularly trained in the assessment and treatment of PTSD. There are sufficient numbers of well-trained psychologists to meet the needs of expansion if some of the problems involved in the recruitment and retention of psychologists are addressed.

4. Would you support the idea of central funding for PTSD treatment center as opposed to funding as part of each VA medical center's annual budget allocation? If not, why not?

Programs for the care of veterans need to be developed at the local level. Local needs, based on density of the veteran population and minority concerns should trigger the medical centers to develop appropriate programs to meet these needs. Designated central funding is helpful to stimulate the growth of needed programs. There is also a need for DVACO to continue to monitor PTSD program spending for at least the first few years of initial funding. We support the concept of designated funding for identified patient care needs and the monitoring of these funds to ensure their appropriate use. In addition, we are supportive of an initiative for the Chief Medical Director's Special Committee to develop a well-studied, research-based national plan.

THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

1990

The Honorable G. V. (Sonny) Montgomery
Chairman, Committee on Veterans' Affairs
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Enclosed please find the responses to questions submitted by you and Representative John Paul Hammerschmidt following the Subcommittee on Hospitals and Health Care's June 28, 1990, hearing on DVA delivery of mental health care services and H.R. 3037. A copy of the responses has been provided to Representative Hammerschmidt.

Sincerely yours,

Edward J. Derwinski

Enclosure
EJD/flc

33-896 0 - 90 - 8

CONGRESSMAN MONTGOMERY

Question: 1. Due to the increasing number of veterans seeking treatment for PTSD and a shortage of resources, the Department of Veterans Affairs (VA) has significantly reduced its length of stay for inpatient PTSD treatment. Has this reduction led to a higher recidivism rate among those veterans who have received treatment?

Answer: Specific information on recidivism of patients who have received inpatient PTSD treatment is not currently available. This would require tracking individual patient's care by Social Security number. The Chief Medical Director's Special Committee on PTSD is working on a similar project with data to be available in their Seventh Annual Report (February 1991). A rough estimate of readmission rates for veterans with PTSD can be derived from the ratio of individual patients to discharges for patients with a PTSD diagnosis. This information, from the Patient Treatment Files shows an increase from 1.51 admissions per patient in FY 1986 to 1.60 in FY 1989.

Question: 2. At the hearing, the balance between the capacity for inpatient and outpatient care for PTSD was discussed. Please elaborate on how you would recommend the distribution of any new PTSD treatment monies between inpatient units, outpatient units, Vet Centers, outreach efforts, and other types of care.

Answer: Our planning model currently features a balance of funds for new initiatives of 25 percent for specialized PTSD inpatient units, 55 percent for outpatient PTSD teams at medical facilities, and 20 percent for Vet Centers. The balance for FTE distribution, in the planning model, is 24 percent for specialized inpatient units, 52 percent for PTSD teams at medical facilities, and 24 percent for Vet Centers.

Question: 3. What are your views (including data if available) on the availability of staff for PTSD treatment if such treatment capacity were expanded as proposed in H.R. 3037 for the following: inpatient units, outpatient units, Vet Centers, other?

Answer: The major problem would be in recruitment of staff and in their training. We know from the ongoing evaluation of PCTs that for new PCTs, although after six months 81 percent of their staff was hired, they had the greatest difficulty in hiring psychiatrists and, to a lesser extent, psychologists. As of March 31, 1990, only 51 percent of psychiatrist positions had been filled. It is believed that this is to a considerable degree due to the pay differential between VA and its local competitors. The need for new staff to be trained in PTSD treatment is less of a problem, because some staff may have PTSD treatment experience already and VA training programs are operational. These training programs will continue to train new staff and to update existing staff on new findings in PTSD. Hiring and training factors are reasons for gradual program expansion in PTSD. With regard to Vet Centers, new staff would be recruited in the various employment categories. We would not expect any major difficulties in obtaining staff for Vet Centers.

Question: 4. Would you support the idea of central funding for PTSD treatment centers as opposed to funding as part of each VA medical center's annual budget allocation? If not, why not?

Answer: No, we do not support the idea of centralized funding for PTSD treatment centers. The present decentralized management system provides local management the ability to set priorities with respect to providing a wide variety of medical care services within a given set of resources. To isolate funding for special programs would limit the flexibility and autonomy of Medical Center leadership in managing their facilities' resources.

Question: 5. To what extent (in terms of percent of veterans who can be treated, or in some other comparative terms) can VA rely on Vet Centers to treat PTSD?

Answer: The National Vietnam Veterans Readjustment Study indicated that approximately 50 percent of Vietnam veterans with post-traumatic stress disorder (PTSD) do not have any of the other measured psychiatric disorders which the study measured. The study also indicated that there are veterans with some PTSD symptoms but not the full diagnostic picture, who have readjustment difficulties, who are suitable for Vet Center services. We estimate that half of veterans with PTSD can be successfully assisted at Vet Centers. With regard to specific localities, geographical considerations and workload have to be taken into consideration. Vet Centers and VAMC PTSD programs are complementary in that different types of patients are seen in these two settings, with VAMCs caring for the more severely disabled patients. Vet Centers and VAMC inpatient and outpatient programs are all essential links in a continuum of care for PTSD that matches patient needs with the treatment mode that can most efficiently meet those needs.

Question: 6. Given the existing pool of resources, can VA expand its treatment of PTSD without adversely affecting other mental health programs?

Answer: Clearly, given a fiscal environment characterized by constrained resources, nothing new can be instituted without giving up something else. Whether decreased services would be manifested in mental health programs or in fewer resources for other VA health care programs is unclear, but some diminished services would be expected.

Question: 7. Please explain how veterans with PTSD would find their way through the array of services offered by the VA, particularly how do the Vet Centers and inpatient PTSD treatment settings work together.

Answer: In the developing spectrum of VA PTSD services -- Vet Centers, PTSD clinical teams at medical facilities, specialized inpatient units, and general psychiatric clinics and inpatient services, the various elements have established close working relationships which support the objective of helping veterans find their way with relative ease. Also, elements of the PTSD spectrum refer veterans relatively smoothly, and there have been very few problems reported in the collaborative relationships which have been established. Concerning Vet Centers and specialized PTSD inpatient units specifically, these units have good working relationships with the Vet Centers which refer veterans to them, and also the inpatient units frequently refer discharged veterans to the Vet Centers for post-discharge followup care.

Question: 8. You stated that VA treated 200,000 inpatients and 5 million outpatients in FY 1989. If H.R. 3037 were enacted without specific additional funds, how many of these patients would be unable to receive care in the future?

Answer: Any requirement for new program initiatives without the provision of additional resources would certainly lead to reduction of some other services. It is impossible at this time to say where or how many veterans would be affected.

CONGRESSMAN HAMMERSCHMIDT

Question: 1. What is the average waiting time for a veteran diagnosed with PTSD before the individual is able to enter a treatment programs?

What are the reasons for these delays and what is the Department doing to rectify the situation?

Answer: The average waiting time for treatment in a Specialized Inpatient PTSD Unit (SIPU) in FY 1990 is 2.8 months. A survey of twelve of the sixteen SIPUs operational in early 1990 revealed that five of these units had no waiting list. That veterans are on a SIPU waiting list, however, does not mean that they are not getting care. Once identified and diagnosed with PTSD, the veteran usually begins a series of individual and/or group therapy sessions while awaiting SIPU admission.

One reason for admission delays is that some of the SIPUs have cohort admissions, i.e., bringing a group of patients into the inpatient treatment program at the same time. This practice promotes bonding betweem patients decreases alienation among group members. There is no indication for changing the cohort admission approach because there is no evidence that it is not a valid aspect of PTSD care. The PTSD program evaluation that has been initiated may clarify this issue.

Another reason for delays is the volume of patients seeking treatment in a limited number of programs. To cope with the volume of patients seeking treatment, four new SIPUs are planned for FY 1990 and it is anticipated that more SIPUs will be developed through VA's strategic planning process.

Question: 2. Does VA currently have the resources necessary to treat all veterans for whom clozaril is clinically indicated? Where would the resources come from and what impact would a transfer or resources have on other health programs?

Answer: It has been estimated that nearly 3,000 veterans with schizophrenia who are currently receiving VA care could be candidates for clozapine. At $9,000 per patient per year, this could result in an expenditure of $27.0 to $30.0 million in medication and monitoring costs. Resources expended for clozapine treatment would not be available for other programs, but where these impacts would occur is not possible to determine. The most likely short-term scenario is that only a limited number of patients in the system will be able to receive clozapine at this time. It is interesting to note that in Sandoz's testimony, they indicated that they were interested in looking into "potential pilot projects" to test providers' capability to monitor patients on Clozaril. Sandoz has not discussed this notion with VA. Nevertheless, we reject the premise that the VA health care system should subject its patients to monitoring by a commercial vendor, as a condition of VA purchasing its product.

Question: 3. The VA has clearly been in the forefront of PTSD research and treatment models. What contribution has the VA's efforts made to the general population?

Answer: With regard to our experiences since 1979 with Vet Center services, they have demonstrated the effectiveness of peer group therapy in multiple communities. This model has become a leading element in the treatment of PTSD. Also, at a number of locations, the centers have provided consultation and education directly to mental health professionals in military installations, in correctional facilities, and in private sector or non-VA local governmental mental health clinics. Such education of non-VA professionals has been an important component of the Vet Centers' mission since implementation, and the result is that many more veterans are able to receive effective treatment for PTSD from non-VA sources. Vet Center staff also are called upon by local community mental health and law-enforcement groups to assist in response to community disasters and crises. VA has participated in educational programs

on PTSD that have included non-VA clinicians who treat a general population (i.e., American Psychiatric Association (APA) Annual Meetings; Society for Traumatic Stress Studies). One of the missions of VA's National Center for PTSD (NCP) is to disseminate information on VA clinical research to other, non-VA caregivers. The NCP is doing this through a number of initiatives including APA presentations, and the development of an on-line bibliography on PTSD. It should also be noted that VA Medical Center and readjustment counseling clinicians from across the nation came to the assistance of local mental health agencies providing post-disaster counseling at the time of the 1989 Loma Prieta earthquake.

Question: 4. Approximately 40% of all VA beds are occupied by veterans who suffer from psychological disorders and yet, less than 10% of VA's research resources are applied to mental health research. Do you believe the Department needs to place more emphasis on mental health research?

Answer: Research on mental illness is highly important, however, the specific question of whether VHS&RA should selectively increase research in mental illness requires careful analysis. Indeed, one of the major tasks of the VA Advisory Committee for Health Research Policy is to provide that analysis. This issue is complicated because it involves not only the obvious need for research that will improve the treatment of veterans and others with psychiatric disorders, but also the opportunities and capabilities of VA scientists to conduct mental illness research.

It is an oversimplification to suggest that medical research funding in any given area should be directly proportional to the percentage of VA patients with a related diagnosis. The fact of multiple diagnoses for each veteran patient would make a systemat distribution of funds on this basis, impossible. The distribution of research funds must take into account such factors as the state of knowledge in a given field, the methodological feasibility of a given type of research, and the availability of research-trained investigators who are qualified to develop and conduct meritorious studies. Taking these factors into consideration, the Advisory Committee for Health Research Policy has been examining the desirability of targeting specific areas in medical research for special funding and attention. The results of the Committee's review will be available shortly.

Funding support for research in mental illness, as a part of the total medical research program in VA, has been affected by the steady reduction in medical research support generally, in recent years. Mental illness research should be increased as part of the overall increase for all VA medical research. VA expects to benefit from more specific guidance from the Secretary's Advisory Committee regarding additional VA support for mental illness research.

Question: 5. The Research Triangle Institute identified approximately 800,000 veterans who have symptoms of PTSD. Do all veterans with symptoms require treatment? Do we have any way of identifying the number of veterans who have symptoms but do not require treatment?

Answer: Not all veterans with symptoms for PTSD require treatment. However, in view of the length of time which has elapsed since Vietnam veterans experienced combat during the war, it seems likely that the healing effect of time itself has largely come to an end, and the majority of those currently with symptons, probably require treatment. There is no way to identify precisely the number of veterans with symptons who do not require treatment.

Question: 6. The average age of the Vietnam veteran is about 45 years. What relationship does aging have to the purpose of readjustment counseling and the future of the Vet Centers?

Answer: Post-traumatic stress disorder appears to be a chronic readjustment problem in many cases. With the episodic exacerbation of symptoms among veterans with chronic PTSD, Vet Centers should very likely continue to serve as a highly valued, clinically appropriate, and cost-effective alternative to the use of more restrictive and costly inpatient treatment resources. The cost-effectiveness of Vet Centers is noteworthy, particularly when all units of services (visits, outreach time, travel time for direct services, and brokering of services on behalf of veterans from non-VA sources) are considered. It appears unlikely that the increasing age of the Vietnam veteran population will result in any sharp decrease in demand and need for Vet Center services, although there may be a gradual decrease over time. Although VA services are helping to reduce the burden of pain and suffering in veterans with PTSD, the chronicity of the condition appears to be a legacy of the long delay which occurred after the Vietnam War and before services began to be provided.

THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

SEP 18 1990

The Honorable G. V. (Sonny) Montgomery
Chairman, Committee on Veterans' Affairs
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Enclosed please find the responses to questions submitted by you and Representative John Paul Hammerschmidt following the Subcommittee on Hospitals and Health Care's June 28, 1990, hearing on VA delivery of mental health care services and H.R. 3037. A copy of the responses has been provided to Representative Hammerschmidt.

Sincerely yours,

Edward J. Derwinski

Enclosure
EJD/flc

CONGRESSMAN MONTGOMERY

Question: 1. Please provide for the record the results of your study of the need and recommended location of treatment resources for PTSD.

Answer: The data collection and analyses begun by the Special Committee in 1986 include demographic and clinical information about veterans treated for PTSD in VA general psychiatry inpatient units and outpatient facilities, and Vet Centers. This data base provides the Special Committee with the ability to review many components of care in association with any particular site of care.

The primary purpose of our 1986 study, which will be repeated in October 1990, was to determine how many Vietnam era veterans with PTSD received outpatient care for psychiatric, substance abuse, social, behavioral, and occupational problems. Data were obtained from three VA treatment areas: (1) the computerized VA Patient Treatment File (PTF) of 1984 and 1985 inpatient psychiatry ward discharges; (2) the 1986 Mental Health Outpatient Survey of veterans in VA mental health outpatient programs; and (3) the 1986 Vet Center Survey of veterans seen in Vet Centers. In 1986, data from each VA Medical District were also compared with the projected geographic distribution of Vietnam era veterans, as derived from Bureau of Census figures. Results from the 1986 study were published in Chapter 2 of the Third Annual Report of the Chief Medical Director's Special Committee on PTSD (February 1987). (Copies of the report are available if desired.)

Since that time, the Special Committee has continued to analyze usage rates for VA inpatient services over a four-year period (FY 1985-1988) by Vietnam veterans who had a recorded diagnosis of PTSD. Data from our 1986 surveys can be aggregated with these statistics. As analyses continue, reports are being prepared on the findings.

The first objective of these studies is to provide a profile of the geographic distribution of the Vietnam veterans estimated to have current PTSD. The 1980 Census data, the VA PTF, and the NVVRS prevalence estimates for current PTSD were used to construct PTSD prevalence estimates for Vietnam era veterans.

The second objective is to combine prevalence data and VA inpatient data to provide a comprehensive historical profile of VA inpatient health care services utilization by Vietnam veterans who have a recorded diagnosis of PTSD, including how these rates vary by geographic area, principal diagnosis for the inpatient episode, racial/ethnic group, and gender. The resulting profiles will describe:

a. the proportion of the Vietnam veterans with PTSD who use VA inpatient services;

b. the number of PTSD-related VA inpatient discharges for an average Vietnam era veteran;

c. the number of different VA admitting hospitals used by an average Vietnam veteran for PTSD-related care;

2.

d. the tendency or need for Vietnam veterans to seek PTSD-related care at a VA hospital located out of the geographic service area where they reside; and

e. the extent to which VA hospitals in a specific area are providing inpatient PTSD-related care to Vietnam era veterans who reside in some other area.

The next Annual Report of the Chief Medical Director's Special Committee on PTSD will provide preliminary information from our October 1990 survey of VA mental health outpatient and Vet Center services, as well as a complete report on the serial inpatient services usage data. In general, analyses are showing substantial area differences in the prevalence of PTSD and user rates for PTSD-related services.

While these data represent only a small proportion of the total population in need of treatment for PTSD, it would be possible to make some tentative statements about the extent to which PTSD patients are recurrrent users of VA services, as well as statements about the need for and recommendations for the location of treatment resources for PTSD. The Special Committee would wish to withhold making definitive statements until data from our October 1990 surveys are analyzed, so as to provide current information that can be used for strategic planning and rational resource allocation decisions.

CONGRESSMAN HAMMERSCHMIDT

Question: 1. What would you consider a safe way of making clozapine available to veteran patients without the extreme cost which is currently inherent with the use of the drug?

Answer: VA has developed a system that is as safe as CPMS and costs less, but which was rejected by Sandoz Pharmaceuticals Corporation, the manufacturer of clozapine. The VA "Patient Management Protocol for the Use of Clozapine" is described in the undistributed March 16, 1990, Draft of VHS&RA Circular 10-90-029, and requires formation of a clozapine treatment team headed by the Chief of Psychiatry Service, with responsibilities that would ensure the safe and appropriate use of clozapine; and implementation of a computerized monitoring software that would "lock out" prescriptions where the white blood cell (WBC) count is too low, absent, or rapidly descending. (A copy of the draft circular is available if desired.)

It is estimated that more than 75 percent of the cost associated with prescribing clozapine results from the manufacturer's Clozaril Patient Management System (CPMS), which ties the purchase of clozapine with a system to perform blood testing. The Food and Drug Administration (FDA) has stated that:

> Although Sandoz may have chosen a specific vendor to implement the CPMS, FDA considers it compatible with the current labling for Sandoz to agree to provide Clozaril through other entities, public or private, that have made specific arrangements to assure that each patient receives weekly white blood cell monitoring as a precondition for dispensing the drug to that patient. (March 1990 letter from FDA to the American Pharmaceutical Association.)

If the VA Clozapine Patient Management Protocol (CPMP) was implemented, the total cost of monitoring and prescribing clozapine would be reduced from $9,000 per patient per year to approximately $2,000 per patient per year. This cost to VA would include the cost of the WBC test (approximately $55.00 per year), the cost of the drug alone ($1,820-2,080 per year, based on the cost of clozapine in Europe), and related laboratory and pharmacy expenses (approximately $200 per year). For the 3,600 patients estimated by VA who might be candidates for clozapine treatment, this would represent a total; cost of approximately $7,200,000 per year, as compared with $32,400,000 with CPMS; or a cost that is one fourth of the cost when Sandoz's CPMS is used.

Question: 2 On page 4 of your testimony, you mention that the Special Committee on PTSD conducted a four-week survey to determine the extent to which PTSD patients are recurrent users of VA services.

Could you tell the Subcommittee what the results of the survey were?

2.

Answer: The data collection and analyses begun by the Special Committee in 1986 include demographic and clinical information about veterans treated for PTSD in VA general psychiatry inpatient units and outpatient facilities, and Vet Centers. This data base provides the Special Committee with the ability to review many components of care in association with any particular site of care.

The primary purpose of our 1986 study, which will be repeated in October 1990, was to determine how many Vietnam era veterans with PTSD received outpatient care for psychiatric, substance abuse, social, behavioral, and occupational problems. Data were obtained from three VA treatment areas: (1) the computerized VA Patient Treatment File (PTF) of 1984 and 1985 inpatient psychiatry ward discharges; (2) the 1986 Mental Health Outpatient Survey of veterans in VA mental health outpatient programs; and (3) the 1986 Vet Center Survey of veterans seen in Vet Centers. In 1986, data from each VA Medical District were also compared with the projected geographic distribution of Vietnam era veterans, as derived from Bureau of Census figures. Results from the 1986 study were published in Chapter 2 of the Third Annual Report of the Chief Medical Director's Special Committee on PTSD (February 1987). (Copies of the report are available if desired.)

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e. the extent to which VA hospitals in a specific area are providing inpatient PTSD-related care to Vietnam era veterans who reside in some other area.

The next Annual Report of the Chief Medical Director's Special Committee on PTSD will provide preliminary information from our October 1990 survey of VA mental health outpatient and Vet Center services, as well as a complete report on the serial inpatient services usage data. In general, analyses are showing substantial area differences in the prevalence of PTSD and user rates for PTSD-related services.

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THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

The Honorable G. V. (Sonny) Montgomery
Chairman, Committee on Veterans' Affairs
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Enclosed please find the responses to questions you submitted to Mr. Fred D. Gusman following the Subcommittee on Hospitals and Health Care's June 28, 1990, hearing on Post Traumatic Stress Disorder and H.R. 3037.

Sincerely yours,

Edward J. Derwinski

Enclosures
EJD/flc

Before the enactment of Public Law 98-528 (which designated the Chief Medical Director's Special Committee on PTSD and the National Center for PTSD), only descriptive data was available on the operations of the VHS&RA's Specialized PTSD services. The Special Committee on PTSD, in accordance with the Public Law, set up its goals for developing a comprehensive database on all VA PTSD activities. I have been responsible for collecting annual survey data on the Specialized Inpatient PTSD Units and preliminary information on the PTSD Clinical Teams (primary responsibility for collection of this data is through Robert Rosenheck, M.D. and NEPEC, with whom I am in collaboration). The Special Committee in turn has provided this data to the Veterans Health Service and Research Administration (VHS&RA), the Chief Medical Director, and the Senate Veterans Affairs Committee in the form of annual updates on the status and present operations of these PTSD services.

1. Due to the increasing number of veterans seeking treatment for PTSD and a shortage of resources, the Department of Veterans Affairs (DVA) has significantly reduced its length of stay for inpatient PTSD treatment. Has this reduction led to a higher recidivism rate among those veterans who have received treatment?

There has been no large scale follow-up study in regards to recidivism and its causes in respect to PTSD. However, treatment providers have identified several variables that could attribute to recidivism among veterans with PTSD.

* We know that this disorder can be chronic and that some veterans will require ongoing treatment beyond inpatient care.

* Historically, there have been limited specialized clinical services for PTSD. This factor has contributed to the previous lack of continuity of care. With the advent of PTSD Clinical Teams (PCTs), new Specialized Inpatient PTSD Units (SIPUs) and other specialized clinical PTSD programs, we are beginning to see a more consistent continuity of care. Thus, the "recidivism" seems to be less of a problem where a continuum of these services are available.

* We now understand that one can have PTSD and other problems (e.g., PTSD and alcoholism). It is this complexity of co-morbidities that provide the opportunity for veterans to relapse, thus requiring additional inpatient or outpatient PTSD treatment. This problem of identifying co-morbidity and developing treatment interventions can be addressed through an educational format. The National Center for PTSD's Clinical Laboratory and Education Division is presently developing a variety of educational media and training activities to address the complexity of providing treatment for PTSD and associated disorders.

* Although there are new PTSD programs, there is still a problem with geographical distribution, particularly in the West and Southwest.

  Presently, the VHS&RA is attempting to alleviate this problem by supporting a coordinated effort through the sharing of information, collaboration of services by all specialized PTSD programs, and

ongoing education between both inpatient and outpatient care.

2. At the hearing, the balance between the capacity for inpatient and outpatient care for PTSD was discussed. Please elaborate on how you would recommend the distribution of any new PTSD treatment monies between inpatient units, outpatient units, Vet Centers, outreach efforts, and other types of care.

The Vietnam Veterans Readjustment Study (RTI) states that of the 3,140,000 Vietnam combat veterans, approximately 450,000 are current cases of PTSD and an additional 350,000 suffer from partial PTSD (meaning they have clinically significant stress reaction symptoms but do not qualify as full PTSD). These numbers describe a population in which readjustment was and continues to be quite difficult.

Of the veterans who seek treatment, it is believed that the majority can be treated as outpatients. We are also aware that there are veterans who require significant PTSD inpatient treatment. As mentioned earlier, PTSD can be chronic and in many cases, these veterans may require both inpatient and outpatient care on a continuum.

Before spending any money, it is necessary to coordinate the existing PTSD services. Once a PTSD needs assessment has been conducted, the geographical location identified, and the lack of existing services to the Vietnam veteran population has been targeted, the following issues should be considered in the planning of any expansion of services:

* The selected medical center's ability to provide new PTSD services;

* The ability to hire staff (if needed);

* The basic clinical knowledge in providing treatment of PTSD;

* Appropriate funds to provide these services.

Currently, there is a concentration of inpatient PTSD services in the Northeastern part of the country. Even with the influx of the 44 PTSD Clinical Teams, areas such as the West and Southwest are still underserved.

Unfortunately, in many cases funding determines what services can be made available. Given the choice of selecting the most cost effective service, outpatient programs would seem to be the logical choice. In support of this, the 1986 Health Science Research and Development report: Mental Health Services for Vietnam Era Veterans with Post-Traumatic Stress Disorder, found that more Vietnam veterans are treated for their PTSD on an outpatient basis than in other types of treatment.

Determining which areas need inpatient or outpatient programs (SIPUs, PCTs, Vet Centers, etc.) should be based upon a needs assessment. There also needs to be a focus on collaboration between services to maximize accessibility.

3. What are your views (including data if available) on the availability of staff for PTSD treatment if such treatment

capacity were expanded as proposed in H.R. 3037 for the following: inpatient units, outpatient units, vet centers, other?

I can only speak to the staffing of SIPUs, PCTs, and PSUs. In my tracking of inpatient PTSD programs and the initial stages of the PCTs, I have found that attracting Ph.D.s, M.S.W.s, and R.N.s seems to be a minimal problem. Hiring physicians is another story due to the competition between public and private sector salaries. Due to the limited resources, programs have been creative in the type of staff hired.

In order to increase the availability of mental health professionals in the field of PTSD, it is imperative that an aggressive educational program be developed to stimulate the interest level and improve the skills of those already in the field and to train those lacking knowledge in the area PTSD. As charged in Public Law 98-528, the National Center for PTSD is to develop such a curriculum in collaboration with existing VHS&RA educational services (Academic Affairs, RMECs, etc.).

4. Would you support the idea of central funding for PTSD treatment centers as opposed to funding as part of each VA medical center's annual budget allocation? If not, why not?

The numerous medical needs that veterans require and the limited operating budgets presents great difficulty for any medical center to choose which services can be provided. All VAMCs make a valiant attempt to meet the needs of their patient constituency.

Centralized funding may be needed to initiate programs, but the most important aspect of these issues is the need to assure accountability for resources.

5. Please discuss the treatment problems associated with dual diagnosis, such as PTSD and substance abuse. Is there a different prediction for successful treatment in cases of these dual diagnoses?

and

6. The PTSD/Substance Abuse programs appear to be an effective way to address the problem of dual diagnosis. Are there any data on the recidivism rate of veterans who have been through these programs compared to veterans who have been through other inpatient PTSD programs.

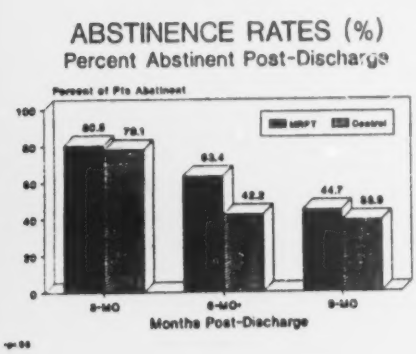
We will address these two questions together based upon available literature and our direct experience with conducting the first clinical demonstration project in PTSD and substance abuse treatment.

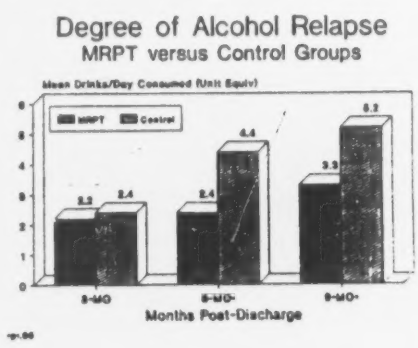
Three principal arguments have been offered regarding the recalcitrance of treating PTSD and the addictions (Abueg & Fairbank, in press). The interaction of the disorders, the convergence of impairment in PTSD and drug and alcohol dependence, and the high relapse rates in each disorder all contribute to the complexity and difficulty in treatment. The interaction problem refers to the clinical observation that the disorders maintain as well as potentiate one

another. The convergence of impairment argument refers to the manifold overlap in life dysfunction in PTSD as well as in alcoholics and drug addicts. Skills deficits contribute to failures to cope when faced with high-risk situations. Third and last, relapse rates in the respective disorders are high post-treatment. Although relapse data on the dually diagnosed are sparse, it stands to reason that concurrent problems will not improve maintenance of gains. A number of researchers have begun to attend to these issues in their reviews of the literature (Keane et. al., 1988, Kosten & Krystal, 1988); actual treatment outcome and process studies are nearly nonexistent. Below is a summary of current research which directly bears on relapse rates in PTSD-alcoholics, treatment efficacy, and precipitants to relapse.

The initial success of the first formal research study examining differential outcome for those treated with modified relapse prevention training (MRPT) versus those not treated with MRPT were presented at two professional conferences in 1989 (Society for Traumatic Stress Disorder in October at the Association for the Advancement of Behavior Therapy (AABT) in November (Abueg, Kriegler, Falcone, Dondershine & Gusman, 1989). Manuscripts are currently under submission to scientific journals.

The two most striking results of the Menlo Park treatment outcome study are presented in graphic form below:





First, the figure at left indicates that the 12-session intervention showed an impact on patients by forestalling a return to drinking in a significant proportion of treated patients versus controls. While these data are extremely encouraging, the convergence of relapse rates at 9 month follow-up suggest the need for additional intervention as well as a deeper understanding of the process of returning to drinking.

The figure on the right illustrates a different and quite important finding. The average number of drinks per day (controlled for type of alcohol and volume) remains low for the treated group as opposed to the control group. Thus, these data suggest that an additional intervention which focuses on how PTSD and alcoholism interact, cannot only forestall relapse but can mitigate the severity of relapse when it does occur.

Another study examining the precipitants to alcohol relapse will be presented in a symposium at the

American Psychological Association in Boston in August 1990 (Abueg, Chun & Lurie, 1990). PTSD-alcoholics in that study report that their PTSD symptoms often act as precipitants to their return to drinking-- in particular, their sleep loss, anxiety, and reexperiencing symptoms. We have proposed that these patient perceptions of relapse must be directly addressed in efficacious, integrative interventions.

Formal process and outcome studies are also underway. These will examine an integrated treatment model of service delivery based on recent theorizing (see Abueg & Fairbank, in press). Treatment that emphasized the patient's stage of change as well as their vulnerability to relapse may hold the greatest promise for enduring intervention effects. Initial data will be forthcoming by the spring of 1991.

In summary, PTSD substance abusers are quite difficult to treat. Initial research shows the relapse prevention training can delay relapse in PTSD-alcoholics. Finally, we reviewed findings which indicated that integrative treatment is critical in providing services to those veterans.

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Abueg, F.R., Chun, K., & Lurie, D. (1990, August). Precipitants to alcohol relapse among PTSD-alcoholics. In T. Keane (Chair) Recent Advances in PTSD Research, (PTSD) Symposium conducted at the annual meeting of the American Psychological Association, Boston.

Abueg, F.R., & Fairbank, J.A., (in press). Treating PTSD-substance abuser; a multidimensional stage model. In P. Saigh (Ed.), Behavioral treatment of post-traumatic stress disorder. N.Y.: Wiley & Sons.

Abueg, F.R., Kriegler, J., Falcon, H., Dondershine, H. & Gusman, F. (1989, November). Relapse prevention training with PTSD-alcoholics: A treatment outcome study with one year follow-up. In F. Abueg (Chair), Co-morbidity in traumatic stress disorders with special attention to substance abuse and dependence. Symposium conducted at the annual meeting of the Association for Advancement of Behavior Therapy, Washington, D.C.

Keane, T.M., Gerardi, R.J., Lyons, J.A., & Wolfe, J. (1988). The interrelationship of substance abuse and post-traumatic stress disorder. In M. Galanter (Ed.), Recent developments in alcoholism, Vol. 6. N.Y.: Plenum Press.

Kosten, T.R., & Krystal, J. (1988). Biological mechanism in post-traumatic stress disorder: Relevance for substance abuse. In M. Galanter (Ed.), Recent developments in alcoholism, Vol. 6. N.Y.: Plenum Press.

7. What is the average waiting time for inpatient PTSD treatment? Are any of those waiting Category A veterans?

As of May 1990, there were approximately 332 veterans waiting for screening and 576 waiting for admission to inpatient treatment. The length of wait ranges from as little as two weeks to as long as one year for admission to treatment, with an average at approximately 2 - 3 months. To my knowledge there are Category A veterans on these waiting lists.

8. Would you discuss the use of day treatment programs as a means of treating veterans who may not need the intensive treatment offered on an inpatient basis, but who need more than limited treatment offered on an outpatient basis?

As stated earlier in my response to question two, outpatient day treatment programs seem to provide the widest range of treatment and accessibility for the veteran. Specially designed day treatment programs for PTSD can provide services to veterans who require more than the traditional one-hour outpatient visit, but less than the intensive PTSD inpatient programs. Day treatment programs can also serve as a link to other specialized PTSD programs in the continuum of care model.

9. What is the role of the Vet Center program in PTSD treatment? How does it relate to the inpatient program?

Vet Centers have provided multiple outpatient services for Vietnam veterans. They have played an important role in reaching these veterans who might not seek traditional VA PTSD services. As part of their services, Vet Centers provide referrals to SIPUs, other VAMC services, and community resources.

In terms of their relationship to inpatient programs, they often help complete the continuum of care so veterans can still receive treatment after discharge from inpatient units.

10. Do PTSD programs share information on veterans who receive treatment for PTSD, such as whether or not they have been treated for PTSD before?

Although some SIPUs contact each other regarding patients, there currently is no formal process for sharing patient information. The information that is received is often inadequate due to:

* Patients not providing complete information on prior hospitalizations.
* The delinquency in accessing patient records from other VAMCs.
* The lack of a formal process of tracking prior hospitalizations of these patients.

It has been an ongoing recommendation of mine that a more collaborative relationship be developed between the VHS&RA Specialized PTSD services in order that important clinical information not be lost.

This is now beginning to be addressed by VHS&RA through Dr. Errera's office in Mental Health and Behavioral Sciences Service (MH&BSS). Examples include:

* National PTSD conference call for all PCTs originated in Dr. Errera's office in MH&BSS.
* Dr. Robert Rosenheck and NEPEC's data collection from all SIPUs and PCTs.
* The National Center for PTSD's educational activities for VHS&RA PTSD services.

In addition, Dr. Errera's office is in the process of developing a plan that will link all SIPUs. This plan will be similar to what is being done for PCTs.

Through the support and leadership of Dr. Errera and MH&BSS, I am optimistic that this will be the beginning of a coordinated and collaborative effort between all VHS&RA PTSD services.

DEPARTMENT OF VETERANS AFFAIRS
Medical Center
2215 Fuller Road
Ann Arbor MI 48105

In Reply Refer To: 506/116A

Hon. G.V. (Sonny) Montgomery, Chairman
Committee on Veterans' Affairs
338 Cannon House Office Building
Washington, D.C. 20515

Dear Congressman Montgomery:

As requested, enclosed are responses to the additional questions forwarded to me following my testimony before the Subcommittee on Hospitals and Health Care on June 28, 1990. Thank you for the opportunity to present this additional information to the subcommittee.

Please feel free to contact me at (313) 930-5994 if there is further information I might provide to the subcommittee concerning these matters.

Sincerely yours,

Spencer P. Falcon, M.D.
Chairman
Chief Medical Director's
Special Committee on PTSD

Enclosure

QUESTIONS SUBMITTED BY HONORABLE JOHN PAUL HAMMERSCHMIDT
TO DR. SPENCER FALCON
AT THE SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE
JUNE 28, 1990
PTSD

1) WHAT WOULD YOU CONSIDER A SAFE WAY OF MAKING CLOZAPINE AVAILABLE TO VETERAN PATIENTS WITHOUT THE EXTREME COST WHICH IS CURRENTLY INHERENT WITH THE USE OF THE DRUG?

VA has developed a system that is as safe as CPMS and costs less, but which was rejected by Sandoz Pharmaceuticals Corporation, the manufacturer of clozapine. The VA "Patient Management Protocol for the Use of Clozapine" is described in the undistributed March 16, 1990 DRAFT of VHS&RA Circular 10-90-029, and requires formation of a clozapine treatment team headed by the Chief of Psychiatry Service with responsibilities that would ensure the safe and appropriate use of clozapine; and implementation of a computerized monitoring software that would "lock out" prescriptions where the white blood cell (WBC) count is too low, absent, or rapidly descending. A copy of that DRAFT Circular will be made available to you if you so desire.

It is estimated that more than 75% of the cost associated with prescribing clozapine results from the manufacturer's Clozaril Patient Management System (CPMS), which ties the purchase of clozapine with a system to perform blood testing. The Food and Drug Administration (FDA) has stated that:

> Although Sandoz may have chosen a specific vendor to implement the CPMS, FDA considers it compatible with the current labeling for Sandoz to agree to provide Clozaril through other entities, public or private, that have made specific arrangements to assure that each patient receives weekly white blood cell monitoring as a precondition for dispensing the drug to that patient.

(March 1990 letter from FDA to the American Pharmaceutical Association.)

If the VA Clozapine Patient Management Protocol (CPMP) was implemented, the total cost of monitoring and prescribing clozapine would be reduced from $9,000 per patient per year, to approximately $2,000 per patient per year. This cost to the VA would include the cost of the WBC test (approximately $55.12 per year), the cost of the drug alone ($1820-2080 per year, based on the cost of clozapine in Europe), and related laboratory and pharmacy expenses (approximately $200 per year). For the 3,600 patients estimated by VA who might be candidates for clozapine treatment, this would represent a total cost of approximately $7,200,000 per year, as compared with $32,400,000 with CPMS; or a cost that is almost one-fourth of the cost when Sandoz's CPMS is used.

Response of Spencer P. Falcon, M.D. 2.

2) ON PAGE 4 OF YOUR TESTIMONY, YOU MENTION THAT THE SPECIAL COMMITTEE ON PTSD CONDUCTED A FOUR-WEEK SURVEY TO DETERMINE THE EXTENT TO WHICH PTSD PATIENTS ARE RECURRENT USERS OF VA SERVICES.

COULD YOU TELL THE SUBCOMMITTEE WHAT THE RESULTS OF THE SURVEY WERE?

and

QUESTION SUBMITTED BY HONORABLE G.V. (SONNY) MONTGOMERY
TO DR. SPENCER FALCON
AT THE SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE
JUNE 28, 1990
PTSD

1) PLEASE PROVIDE FOR THE RECORD THE RESULTS OF YOUR STUDY OF THE NEED AND RECOMMENDED LOCATION OF TREATMENT RESOURCES FOR PTSD.

The data collection and analyses begun by the Special Committee in 1986 include demographic and clinical information about veterans treated for PTSD in DVA general psychiatry inpatient units and outpatient facilities, and Vet Centers. This database provides the Special Committee with the ability to review many components of care in association with any particular site of care.

The primary purpose of our 1986 study, which will be repeated in October 1990, was to determine how many Vietnam Era veterans with PTSD received outpatient care for psychiatric, substance abuse, social, behavioral, and occupational problems. Data were obtained from three VA treatment areas: (1) the computerized DVA Patient Treatment File (PTF) of 1984 and 1985 inpatient psychiatry ward discharges; (2) the 1986 Mental Health Outpatient Survey of veterans seen in VA mental health outpatient programs; and (3) the 1986 Vet Center Survey of veterans seen in Vet Centers. In 1986, data from each VA Medical District were also compared with the projected geographic distribution of Vietnam Era veterans, as derived from Bureau of Census figures. Results from the 1986 study were published in Chapter 2 of the Third Annual Report of the CMD's Special Committee on PTSD (February 1987). I would be pleased to provide you with additional copies of the report if needed.

Since that time the Special Committee has continued to analyze usage rates for VA inpatient services over a four-year period (FY 1985-88) by Vietnam veterans who had a recorded diagnosis of PTSD. Data from our 1986 surveys can be aggregated with these statistics. As analyses continue, reports are being prepared on the findings.

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b. the number of PTSD-related DVA inpatient discharges for an average Vietnam Era veteran;

c. the number of different DVA admitting hospitals used by an average Vietnam veteran for PTSD-related care;

d. the tendency or need for Vietnam veterans to seek PTSD-related care at a DVA hospital located out of the geographic service area where they reside;

e. the extent to which VA hospitals in a specific area are providing inpatient PTSD-related care to Vietnam Era veterans who reside in some other area.

The next Annual Report of the CMD's Special Committee on PTSD will provide preliminary information from our October 1990 survey of VA mental health outpatient and Vet Center services, as well as a complete report on the serial inpatient services usage data. In general, analyses are showing substantial area differences in the prevalence of PTSD and user rates for PTSD-related services.

While these data represent only a small proportion of the total population in need of treatment for PTSD, it would be possible to make some tentative statements about the extent to which PTSD patients are recurrent users of VA services, as well as statements about the need for and recommendations for the location of treatment resources for PTSD. The Special Committee would wish to withhold making definitive statements until data from our October 1990 surveys are analyzed, so as to provide current information that can be used for strategic planning and rational resource allocation decisions.

DEPARTMENT OF VETERANS AFFAIRS
Medical Center
950 Campbell Avenue
West Haven CT 06516

August 2, 1990

In Reply Refer To: 689/116A

The Honorable G.V. Montgomery
Chairman
U. S. House of Representatives
Committee on Veterans' Affairs
335 Cannon House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your letter of July 11, 1990 concerning treatment services provided by the Department of Veterans Affairs for Veterans suffering from combat-related Posttraumatic Stress Disorder. I am delighted to respond to the additional questions you have posed and hope that you will continue to request my assistance in the future, if you feel I can be of help.

To provide the most thorough responses possible to your specific questions, I have consulted with my colleague Dr. Robert Rosenheck, Director of the Northeast Program Evaluation Center, and of the Evaluation Division of the National Center for PTSD. Dr. Rosenheck has conducted several recent studies on both length of stay and recidivism in VA Medical Centers, and on the treatment of the dually diagnosed. He is also responsible for the evaluation of the PTSD Clinical Teams (PCT) Program and has given me permission to share some preliminary findings from that evaluation that are of immediate relevance.

As you requested, I have presented the questions (in bold type) before my responses.

Sincerely yours,

Dennis S. Charney, M.D.
Chief, Psychiatry Service

Enclosure

1. Due to the increasing number of veterans seeking treatment for PTSD and a shortage of resources, the Department of Veterans Affairs (DVA) has significantly reduced its length of stay for inpatient PTSD treatment. Has this reduction led to a higher recidivism rate among those veterans who have received treatment?

The number of inpatients treated for PTSD has increased markedly in recent years, but the available data do not suggest this as the principal reason for the reduction in lengths of stay. The principal cause of reduced lengths of stay in VA was the DRG-based Resource Allocation Methodology (RAM).

During the four years before RAM implementation (FY 1981-FY 1984), for example, lengths of stay for all psychiatric disorders in VA increased by 8.1%. During the four years of the RAM, in contrast, psychiatric lengths of stay decreased by 36.9% (or 9.2% per year). Since suspension of the RAM, in September 1988, the decline in psychiatric lengths of stay has slowed considerably, to a rate of only 1.2% per year.

Trends for length of stay for PTSD have generally followed the national trends for other psychiatric disorders. There was a 10% increase in average length of stay for PTSD from FY 1982-FY 1985, a 28.2% decrease from FY 1985-FY 1988 and a 0.6% increase during FY 1989. The RAM stimulated increased workload as well as shortened lengths of stay, but increased workload does not seem to have caused the shortened lengths of stay.

Although average lengths of stay for PTSD dropped markedly from FY 1985 to FY 1989 (from 43 days to 31 days) annual readmission rates have been generally stable. In 1985 7.9% of veterans discharged with a primary diagnosis of PTSD were re-admitted within 14 days, in comparison to 8.8% in FY 1989. This increase in recidivism is modest in comparison with the 28% reduction in length of stay between FY 1985 and FY 1989. It must also be remembered, in interpreting these data, that re-admission is not necessarily a good indicator of clinical outcome.

2. At the hearing, the balance between the capacity for inpatient and outpatient care for PTSD was discussed. Please elaborate on how you would recommend the distribution of any new PTSD treatment monies between inpatient units, outpatient units, vet centers, outreach efforts, and other types of care.

Studies are just beginning, under Dr. Rosenheck's leadership, that will examine the differing clinical problems of VA inpatients and VA outpatients with PTSD. These studies will eventually provide an empirical basis for considering this question. Without better data on the clinical needs and problems of VA inpatients and outpatients with PTSD it is impossible to responsibly identify where funds can most effectively be deployed. In general, it can be said that greater numbers of veterans can be assisted through outpatient treatment, and that more disturbed veterans can be assisted through inpatient treatment. My impression is that augmentation of both types of treatment is needed.

3. What are your views (including data if available) on the availability of staff for PTSD treatment if such treatment capacity were expanded as proposed in H.R. 3037 for the following: inpatient units, outpatient units, vet centers, other?

It is my understanding from Dr. Rosenheck that recruitment for the first 24 PCTs was somewhat slow, especially for psychiatrists. Recruiters apparently found VA salaries to be less than competitive, especially for physicians. However, by the end of the first year of program operation, 88% of the funded staff positions were filled, although only 66% of psychiatrist positions were filled. I have little information on a national basis on the availability of staff for the other PTSD programs. However, at our

medical center staff positions in our inpatient unit and outpatient clinic are considered highly desirable and are easy to fill. Generally, in my opinion, additional funds for the programs listed could and would be used effectively.

4. Would you support the idea of central funding for PTSD treatment centers as opposed to funding as part of each VA medical center's annual budget allocation? If not, why not?

The advantage of central funding is that it assures the resources are utilized as originally intended. On the other hand central funding poses some risk of micro-management. Medical Center Directors must have adequate autonomy to manage their programs effectively. I believe the current approach, in which funds are distributed to medical centers, but monitored centrally, is the most appropriate one.

5. Please discuss the treatment problems associated with dual diagnosis, such as PTSD and substance abuse. Is there a different prediction for successful treatment in cases of these dual diagnoses?

It does appear that veterans suffering from both substance abuse disorders and PTSD have a less successful response to treatment, primarily because their substance abuse interferes with all aspects of their treatment. This is also true for other psychiatric disorders such as depression and schizophrenia. Unfortunately, objective data on the outcome of treatment for such PTSD patients are not yet available. Dr. Rosenheck's reports indicate that approximately 60% of inpatients and 30% of outpatients with a primary diagnosis of PTSD are "dually diagnosed." It is likely that inpatient treatment is particularly important in the treatment of the dually diagnosed because of their special need for structure and supervised abstinence. Specialized half-way house programs might also prove to be an important component of treatment for dually diagnosed veterans with PTSD, although I do not believe we have such programs yet. The evaluation of the new PTSD Substance Use Programs (PSUs) and Substance Use PTSD Teams (SUPTs) will increase our knowledge in this area, but additional treatment outcome research is desperately needed to find better approaches to this problem.

6. The PTSD/Substance Abuse programs appear to be an effective way to address the problem of dual diagnosis. Are there any data on the recidivism rate of veterans who have been through these programs compared to veterans who have been through other inpatient PTSD programs?

Since these programs are just starting, data on their work are not yet available. Data on a pilot program at Menlo Park, using a novel "Relapse Prevention" approach have been encouraging. Mr. Gusman would be more fully informed on the findings from that program.

7. What is the average waiting time for inpatient PTSD treatment? Are any of those waiting Category A veterans?

Mr. Gusman has compiled extensive data on this issue. I do not have any particular information in this area.

8. Would you discuss the use of day treatment programs as a means of treating veterans who may not need the intensive treatment offered on an inpatient basis but who need more than limited treatment offered on an outpatient basis?

Day programs have been implemented by several of the PCTs and more information on their effectiveness should be available during the next year. This is a promising approach to intensive treatment, and is likely to be less costly than inpatient treatment. However, day treatment should be approached cautiously. The most common reason for termination from PCT treatment, among veterans with

fully-diagnosed PTSD, has been difficulty with transportation. Day programs need to make special provision for providing transportation for their patients if they are to be readily accessible.

9. What is the role of the Vet Center program in PTSD treatment? How does it relate to the inpatient program?

The Vet Centers have been, and remain, an important portal of entry into treatment for many veterans. Although my experience is limited, many Vet Centers seem to provide valuable counselling services as well. We must insure, however, that all veterans have access to appropriate medical-psychiatric treatment, especially as more effective pharmacologic agents are identified. Vet Centers and VA Medical Center Programs should be more integrated to guarantee that such comprehensive services are provided. The National Vietnam Veterans Readjustment Study found that only 3.6% of Vietnam Veterans with PTSD had used Vet Centers, as compared with 20.0% who had used any VA services. These data would suggest that many severely affected veterans, those with full-blown PTSD, are finding their way to treatment at VA Medical Centers. A more collaborative relationship between Vet Centers and VA Medical Centers should increase the number of veterans requesting and receiving high quality PTSD treatment.

10. Do PTSD programs share information on veterans who receive treatment for PTSD, such as whether or not they have been treated for PTSD before?

To my knowledge this does not happen as a matter of formal procedure, although good medical practice always dictates review of previous treatment with the involved clinicians whenever possible.

11. There was some initial concern about the bicoastal nature of the National Center for PTSD. Has this created any problems?

The bicoastal nature of the National Center for PTSD has worked extremely well. I have been a principal investigator on at least five other similar "center grants" for psychiatric disorders and none has worked as well as the PTSD Center regarding frequent communications, collaborative projects, and a sense of mission. There are several reasons for this. Supplemental travel money has been provided to permit scientific and educational meetings at each of the sites. There are regularly scheduled weekly conference calls between the center investigators and key personnel. There is functional complementarity between the different sites in terms of patients served, staff expertise, and program design that have enriched the center as a whole. A prime example is the extensive experience in ethnic minority PTSD treatment at Menlo Park facilitating the development of educational, treatment, and research programs at the other center sites.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

The Honorable G. V. (Sonny) Montgomery
Chairman, Committee on Veterans' Affairs
House of Representatives
Washington, D.C. 20515

AUG 09 1990

Dear Mr. Chairman:

This is in response to your letter of July 11, 1990, to Dr. Paul Leber, requesting answers to additional questions for the record of the hearing on June 28, 1990, before the Subcommittee on Hospitals and Health Care.

We have enclosed the requested responses in the format indicated in your letter.

If we can be of any further assistance, please let us know.

Sincerely yours,

Wayne R Mann

Hugh J. Cannon
Associate Commissioner
for Legislative Affairs

Enclosure

QUESTIONS SUBMITTED BY THE HONORABLE JOHN PAUL HAMMERSCHMIDT
TO THE FOOD AND DRUG ADMINISTRATION
AT THE SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE HEARING
JUNE 28, 1990

QUESTION 1: Does FDA analyze the potential economic impact of a new drug prior to approving it?

ANSWER: No. The Federal Food, Drug, and Cosmetic (FDC) Act does not give the Food and Drug Administration (FDA) authority to consider economic impact in its new drug approval decisions.

QUESTION 2: Did FDA analyze the economic impact of Clozaril? If so, what were FDA's findings?

ANSWER: No.

QUESTION 3: Why did FDA allow Sandoz Pharmaceutical Company to have right of approval on monitoring systems such as the VA's?

ANSWER: As the sponsor of the approved new drug application (NDA) for Clozaril, Sandoz has an obligation under the FDC Act to ensure that its product is not and does not become "misbranded" and that Clozaril is distributed only under the conditions of use identified in its labeling. Specifically, Clozaril could be deemed "misbranded" or could be considered an unapproved new drug (i.e., one distributed under conditions of use other than those approved by FDA) if it were distributed under a system that did not ensure that delivery of the drug was conditioned upon each patient's submission to a weekly white blood count. If Sandoz is to honor this obligation, it must have the ability to control the performance of the agents it chooses to employ to distribute Clozaril. Thus, Sandoz was permitted to do what any other firm selling a product is allowed to do; that is, choose the distributor or distributors for its product. Sandoz did not receive or need any special permission to do this.

In the usual course of events, FDA has no interest in controlling, or authority to control, any sponsor's choice of a distributor. Of course, the Agency might become involved, through action against Sandoz or its product, if it became evident that a distributor or other drug supplier, acting as an agent of Sandoz, was failing to distribute Clozaril as specified in its labeling. In addition, State or other Federal laws may place limits on Sandoz's right to choose certain distributors.

QUESTION 4: Is it the intention of FDA that Sandoz be granted exclusivity in monitoring patient response to Clozaril?

ANSWER: No, but it is not entirely a matter of FDA's intentions. As the holder of the NDA, Sandoz is, until such time that an abbreviated NDA for clozapine is approved, the only domestic source of the product. The Agency has no authority to force Sandoz to use agents that it does not elect to use. On the other hand, the Agency has repeatedly stated that its approval of labeling referring to the Clozaril Patient Monitoring System (CPMS) was not and is not an endorsement of a particular provider of health care services, but a generic endorsement of a system of drug distribution and services, a system that might be provided by any number of agents and/or institutions, both public and private. Basically, the Agency would consider any system that competently provided the CPMS services as compatible with approved labeling.

QUESTION 5: Could FDA require Sandoz to re-label the Clozaril packaging?

ANSWER: The Agency can take action if labeling is false or misleading in any particular or the product is not safe for use or not effective in use under the conditions specified in approved labeling.

At present, we find that Clozaril's labeling may be somewhat misleading in that it has contributed to misunderstanding concerning the role of Caremark, that firm that Sandoz has currently arranged to serve as the sole provider of the CPMS services. Current labeling allows the incorrect inference that Caremark is the only possible distribution/monitoring agent that Sandoz can employ when, in fact, other distribution/monitoring systems would be compatible with approved labeling. Accordingly, we have asked Sandoz to modify Clozaril's labeling to remove those portions that we believe contribute to the misleading inferences. At the time that this response was being drafted, Sandoz had not yet responded to our request.

QUESTION: Does FDA believe such re-labeling to be necessary?

ANSWER: Yes, to the extent described immediately above.

QUESTION: What procedures are necessary in order to achieve product re-labeling?

ANSWER: Forcing a reluctant sponsor to revise labeling can present certain regulatory problems. At this point Sandoz has not indicated whether it will voluntarily revise its labeling in response to our request. If Sandoz refuses to comply voluntarily with the requested change, FDA's options include (1) bringing an enforcement action in Federal court on the ground that the drug is misbranded as labeled, (2) withdrawing approval of the drug altogether, or (3) disseminating educational information to physicians and other interested entities. FDA would have to consider which option or options to take, depending on such factors as the likelihood of success with a given option, the resources available to pursue the option, and the importance of the drug.

QUESTION 6: What was the intention of FDA in requiring a patient monitoring system to be in place prior to the administration of Clozaril?

ANSWER: The Agency endorsed a controlled distribution system in order to mitigate the risk of fatality associated with agranulocytosis. This dreaded disorder, which occurs in between 1 and 2 percent of patients treated for a year with Clozaril, can, depending upon the circumstances of its occurrence, be associated with a very high case fatality rate. For example, when Clozaril was first marketed in Finland in the mid-1970s, approximately 50 percent of the patients, who were reported to have Clozaril induced cases of agranulocytosis, died. During more recent U.S. premarketing clinical tests of the product, all 15 of the known patients with Clozaril-induced agranulocytosis recovered. The difference in these outcomes is striking and is due entirely to the recognition that Clozaril causes agranulocytosis in addition to the ability to take appropriate medical intervention early in the course of the condition. Early medical intervention is only possible if agranulocytosis is diagnosed quickly after its onset, which, in turn, is only possible if white blood counts are performed at a weekly interval in every patient.

The importance of weekly white counts cannot be over-emphasized. The risk of fatality in agranulocytosis increases with the duration of the low white count. Unfortunately, the presence of the condition can go undetected because it may produce few signs and symptoms in the patient until signs of an overwhelming infection are present. By then, it is often too late for medical intervention to succeed, as the experience in Finland 15 years ago sadly documents. In contrast, during domestic clinical testing, weekly white counts allowed all cases to be detected early and all patients survived.

Given these facts, the approval of Clozaril was long considered a problematic and risky venture, even in the face of sound evidence documenting its superiority to traditional therapy in some recidivistic patients. Sandoz's proposal to market Clozaril under a distribution system that assured that all patients receiving the drug would, like patients who had participated in premarket testing, have weekly white blood counts, dramatically altered our risk to benefit assessment about whether the benefits of the drug would outweigh its risks after marketing.

In sum, FDA endorsed the critical elements of Sandoz's distribution system (i.e., the conditioning of continued supplies of the drug on weekly white blood cell counts) for Clozaril, because it made it possible to conclude that a valuable, but ordinarily very dangerous product would be "safe for use." Without Sandoz's commitment that a distribution scheme with these elements would be imposed, it is doubtful that this judgement could have been made.